FEAR OF HYPOGLYCAEMIA IN PEOPLE ATTENDING THE CHRISTCHURCH DIABETES CENTRE

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GLOSSARY

Blood glucose level The amount of glucose in the blood measured in $mmolL^{-1}$. In people with out diabetes blood glucose levels are below 6 $mmolL^{-1}$. People with diabetes are encouraged to monitor their blood glucose levels regularly usually, by a *finger prick test*.

Diabetes mellitus A group of metabolic disorders in which glucose metabolism is abnormal.

Fear of hypoglycaemia An anxiety disorder, specific to people with diabetes, in which people have a phobic avoidance of hypoglycaemia.

Finger prick test A self-administered test for blood glucose levels, which involves pricking a finger to obtain a small amount of blood to be analysed in a blood glucose machine.

HbA_{1c} - glycated haemoglobin The clinically recommended index of metabolic control over the previous six to eight weeks. See also *metabolic control*.

Hyperglycaemia A condition in which the blood glucose level is higher than normal (approximately above 7 $mmol^{-1}$). See also metabolic control.

Insulin Dependent Diabetes Mellitus (IDDM) A common usage term to describe people with early onset *type 1* diabetes which sometimes includes people with *type 2* diabetes that are on insulin therapy.

Insulin A hormone produced by the pancreas that acts to regulate blood glucose levels. Synthetic or animal insulin is prescribed for all people with type 1 and people with more advanced type 2 diabetes.

Hypoglycaemia A condition in which blood glucose levels are lower than normal (Approximately below 3 $mmolL^{-1}$). See also *metabolic control.*

Metabolic control People are advised to keep blood glucose levels between 3 and 7 $mmolL^{-1}$. Above this range people become more likely to experience diabetes-related complications associated with *hyperglycaemia* such as retinopathy, peripheral neuropathy, and nephropathy. Below this range (*hypoglycaemia*) there is a risk of coma and in severe cases, death.

Metformin An oral anti-diabetic agent that acts to reduce peripheral insulin resistance resulting in lower blood glucose levels. Metformin does not cause *hypoglycaemia* in therapeutic doses.

Non-Insulin Dependent Diabetes Mellitus (NIDDM) A common usage term to describe people with type 2 diabetes.

Sulphonylureas Oral anti-diabetic agents that act by stimulating insulin release from the pancreas. Four varieties are available in New Zealand; glibenclamide, gliclazide, glipizide and tolbutamide. All sulphonylureas can cause *hypoglycaemia*.

Type 1 diabetes A form of diabetes in which the pancreas does not produce insulin, resulting in a dependence on regular insulin injections for survival. Type 1 diabetes is generally diagnosed in infancy through to young adulthood and the majority of cases have a genetic marker present.

Type 2 diabetes The most common form of diabetes, caused by a resistance and/or a deficit in insulin secretion by the pancreas. It is usually diagnosed in adulthood and is generally caused by lifestyle factors such as diet, weight and lack of exercise.

LIST OF ABBREVIATIONS

Diabetes related terms:

IDDM	Indulin dependent diabetes mellitus
NIDDM	Non-insulin dependent diabetes mellitus

Statistical terms:

M	mean
SD	standard deviation
N	number

ABSTRACT

Fear of hypoglycaemia is an anxiety disorder that is specific to people with diabetes. People with a fear of hypoglycaemia (low blood sugar) typically modify their behaviour (a phobic response) to avoid low blood glucose levels in order to reduce their anxiety. By avoiding the feared situation, the maladaptive avoidance behaviour is negatively reinforced. However, people that keep their blood sugars high are at risk of serious diabetes-related complications. This study investigated the prevalence of fear of hypoglycaemia in people attending the Christchurch Diabetes Centre and considered which factors influence the development and maintenance of fear of hypoglycaemia. It was found that 18% of patients surveyed had a high fear of hypoglycaemia and that in some cases, metabolic control was likely to be compromised. Anxiety and previous experience of hypoglycaemia were the factors that were the most strongly liked to fear of hypoglycaemia.

1. INTRODUCTION

This study was initiated to clarify the anecdotal evidence of diabetes physicians that there appeared to be an association between fear of hypoglycaemia and higher blood glucose levels in patients attending the Christchurch Diabetes Clinic (Joss Tennent, personal communication). Fear of hypoglycaemia is still relatively little studied and there have been no studies published investigating fear of hypoglycaemia in New Zealanders with diabetes.

1.1. Overview of diabetes

1.1.1. Physiology of diabetes

Diabetes mellitus is not a single disease but is a group of metabolic disorders in which glucose metabolism is abnormal (The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 2002). Glucose metabolism in people without diabetes is homeostatic. When blood glucose levels rise above the normal range (between 4 and 8 mmol/L) insulin is automatically released from the pancreas. The insulin acts to reduce excess blood glucose in the blood stream by moving it into muscles (for short-term storage) and fat and liver cells (for long term storage). When glucose levels fall below normal the pancreas releases glucagons, which act to release the stored glucose from fat and liver cells into the blood stream. In people with diabetes this automatic control of glucose is impaired either by an absence or deficiency in insulin release from the pancreas, or a resistance to insulin action that builds up over time. This results in uncontrolled rises in blood glucose (hyperglycaemia) to potentially harmful levels,

which is common to all types of diabetes. Symptoms of hyperglycaemia include polyuria (increased urination), excessive thirst, weight loss and blurred vision. Long-term complications of persistent hyperglycaemia include retinopathy with potential loss of sight, renal failure, peripheral neuropathy increasing the likelihood of ulcers and lower leg amputation, autonomic neuropathy resulting in gastrointestinal, genitourinary and cardiovascular problems, and sexual dysfunction. Therefore it is an important part of diabetes management to maintain blood glucose at levels low enough to avoid these potentially debilitating complications.

1.1.2. Type 1 and Type 2 Diabetes

The two most common forms of diabetes are known as Type 1 and Type 2. In Type 1 diabetes the pancreas does not produce insulin, and therefore these patients are dependent on insulin injections for survival. This form of diabetes is generally diagnosed in infancy through to young adulthood and the majority of cases have a genetic marker present.

Type 2 is the most prevalent form of diabetes and accounts for 85-90% of all diabetes cases in developed countries (Ministry of Health, 1999). Type 2 diabetes is due to a resistance to insulin and or a deficit in insulin secretion. It is usually diagnosed in adulthood, becoming more common with age. This form of diabetes is often undiagnosed for a significant time before it becomes severe enough for the patient to seek treatment, often in response to stress or an illness [ECDCDM], 2000 #75], however, in this time damage due to hyperglycaemia can have already occurred.

It should be noted that although type 1 and type 2 are the terms recommended by the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, (2002), there is common usage of the terms Insulin Dependent Diabetes Mellitus (IDDM) and Non-Insulin Dependent Diabetes Mellitus (NIDDM). Although IDDM is generally used to describe those with the earlier onset, genetically determined, type 1 diabetes it can sometimes include those with type 2 diabetes who are on insulin therapy. NIDDM is only used for patients with type 2 diabetes as all patients that have type 1 should be on insulin therapy. Therefore the cause of the diabetes is less clear when these terms are used.

1.1.3. Diabetes in New Zealand

As diabetes affects a large number of New Zealanders it has become a major focus for health authorities (Health Funding Authority, 2000). It is important for both financial and social reasons to limit the effect of this disease as much as possible. The New Zealand Health Survey (Sarfati & Scott, 2000) found that 1 in 27 New Zealanders has diabetes and that the prevalence is increasing rapidly (Simmons, Harry, & Gatland, 1999). Maori and Pacific Island People are twice as likely as New Zealanders of European descent to have diabetes and it is expected to increase by 97% among Maori and 47% for New Zealanders of European descent over the next 20 years (Health Funding Authority, 2000). The increase in type 2 diabetes has been attributed to an increase in the Polynesian population and in the number of elderly, however the smaller rise in type 1 diabetes is unexplained (Moore & Lunt, 2000).

In Maori and Pacific Island people type 1 accounts for 5% of all diabetes but this rises to 11% in New Zealanders of European descent (Health Funding Authority, 2000). The total number of New Zealanders with type 1 diabetes is estimated to be 10, 500. In the area serviced by the Canterbury District Health Board there is estimated to be almost four and a half thousand people with diabetes, with type 1 diabetes more common in this region than the rest of New Zealand possibly due to a genetic cause (Health Funding Authority, 2000).

1.1.4 . Treatment of diabetes

In mild to moderate cases, type 2 diabetes is managed by diet and other lifestyle changes including exercise, but as the disease progresses, medications to increase the body's sensitivity to insulin such as metformin, sulphonylurea drugs, and insulin may be prescribed (Garber, 1999).

Metformin is an oral anti-diabetic agent (tablet form) that acts to reduce peripheral insulin resistance resulting in lowered blood glucose. Metformin is generally the agent of choice for patients with type 2 diabetes that are unable to control their blood glucose by diet alone. It is sometimes prescribed in conjunction with a sulphonylurea and or insulin. Metformin does not cause hypoglycaemia in therapeutic doses

Sulphonylureas act by stimulating insulin release from the pancreas and are used to treat type 2 diabetes only. There are four types (tablets) available in New Zealand – glibenclamide, gliclazide, glipizide and tolbutamide. All

sulphonylureas can cause hypoglycaemia and patients prescribed these are instructed in hypoglycaemia management.

Insulin is taken by all patients with type 1 diabetes and more advanced type 2 diabetes. It is self-administered by injection between one and four times a day. Regular self-testing of blood glucose levels is required to maintain insulin levels at a therapeutic level. There are at least two kinds of insulin, synthetic and animal insulin, and many varieties with different profiles of insulin action. Therefore, insulin regimes are individualised to suit each patient. Some patients with type 2 diabetes may take metformin and or a sulphonylurea in addition to insulin. Insulin causes hypoglycaemia when there has been insufficient food intake or excessive exercise for the insulin dose administered.

1.1.5. Hypoglycaemia

An important side effect of sulphonylurea drugs and insulin therapy is the risk of hypoglycaemia. Hypoglycaemia occurs when blood glucose falls to a low level and it occurs by either an excess of insulin for the amount of food ingested or a level of physical activity that has used up available glucose. Symptoms of mild hypoglycaemia include shaking, sweating and a rapid heart rate and these can be quickly treated by administration of glucose, often in the form of special tablets or sweets such as jellybeans. In more severe hypoglycaemic episodes, glucose supply to the brain is reduced resulting in symptoms such as lethargy, mental slowing, and eventually coma and death if left untreated. Patients with severe hypoglycaemic episodes generally need assistance from others to administer

treatment, for example high sugar foods or in the most severe cases intravenous infusions of dextrose.

Recurrent hypoglycaemia can have lasting negative effects on cognitive function including reduced ability to process new information, decreased speed of performance and decreased decision-making ability (Frier, 2001; Gold, Deary, & Frier, 1993). Almost all patients who are prescribed insulin experience mild hypoglycaemia at some time and many who take sulphonylurea drugs may also experience hypoglycaemia. As a general rule, patients begin to notice the early symptoms of hypoglycaemia when blood glucose levels are less than 3.0 mmol/l, however, this varies between individuals.

Severe hypoglycaemia is more common in people with type 1 diabetes than type 2 as those with type 2, even when on insulin or sulphonylurea drugs, generally have a more intact counter-regulatory response to low blood sugar levels (Gerich, 2000; Peacy, Robinson, & Bedford, 2000). Ter Braak et al., (2000) found that 40.5% of patients with type 1 diabetes attending an outpatient clinic had experienced at least one episode of severe hypoglycaemia. This is much higher than the 2% of patients with type 2 diabetes who had experienced severe hypoglycaemia in a study by van Staa, Abenhaim & Monerre (1997) reported in (Gerich, 2000). Patients with type 1 diabetes may also lose the ability to recognise the early signs of hypoglycaemia, placing them at a greater risk of severe hypoglycaemia. Gold, MacLeod, & Frier, (1994) found that patients with type 1 diabetes who had an impaired awareness of hypoglycaemia were six times more likely to experience severe hypoglycaemia than those patients with normal awareness.

Hypoglycaemia is an unpleasant and potentially dangerous side effect of diabetes treatment and can disrupt social and occupational functioning in some patients (Richmond, 1996).

1.2. Fear of Hypoglycaemia - A review

A possible link between the unpleasant experience of hypoglycaemia, fear and avoidance of hypoglycaemia, and maintaining elevated blood glucose was first suggested in the late 1970's and early 80's (Weiner & Skipper, 1979; Surwit, Scovern, & Feinglos, 1982). Fear of hypoglycaemia has been described not only in people with diabetes but also in parents of children with diabetes (Macrodimitris & Endler, 2001) and in spouses of patients with diabetes (Gonder Frederick, Julian, Cox, Clarke, & Kovatchev, 1997).

The literature relevant to fear of hypoglycaemia falls into three categories; studies investigating factors that affect glycaemic control, psychosocial factors affecting diabetes management in general, and finally a small body of work that specifically addresses fear of hypoglycaemia. Most of the studies that focus on fear of hypoglycaemia have used the Fear of Hypoglycaemia Scale (HFS) developed by Cox and colleagues (Cox, Gonder-Frederick, Nowacek, & Butterfield, 1987). The HFS measures both behavioural and cognitive (worry) aspects of fear of hypoglycaemia.

1.2.1. Diabetes-related factors

The majority of published studies have focused on either patients with type 1 diabetes only or those with type 2 that take insulin. Few studies have directly

compared type 1 with type 2 diabetes, however, Polonsky, Davis, Jacobson, & Anderson, (1992) found fear of hypoglycaemia to be greater in those with type 1 diabetes.

The effect of previous experience of hypoglycaemia, particularly severe episodes, has been found to increase fear of hypoglycaemia. Irvine, Cox, & Gonder-Frederick, (1992) found that the Behaviour Subscale of the HFS was related to the frequency of previous hypoglycaemia in patients with IDDM. The total HFS score (combining behavioural and cognitive aspects) has been found to have a positive relationship with previous hypoglycaemia (Costea, Ionescu-Tirgoviste, Cheta, & Mincu, 1993; Irvine et al., 1992; Ter Braak et al., 2000) and with the frequency of hypoglycaemia-related hospitalisations (Shiu & Wong, 2000) in patients with IDDM. (Polonsky et al., 1992) also found that previous experience increased fear of hypoglycaemia in participants with type 1 but not in type 2 diabetes. A survey of both type 1 and type 2 diabetes (Thompson, Cummings, Chalmers, Gould, & Newton, 1996) found that those who had experienced severe hypoglycaemia episodes were less likely to want to improve metabolic control, possibly due to fear of hypoglycaemia.

The influence of previous severe hypoglycaemia has also been found to affect the level of fear of hypoglycaemia in parents of children with type 1 diabetes (Macrodimitris & Endler, 2001). This study of fear of hypoglycaemia in parents of children with type 1 diabetes in the United States found that fear of hypoglycaemia was positively correlated with the number of hypoglycaemic seizures during the past year.

Patients with reduced awareness of hypoglycaemia have also been found to score more highly on the HFS Worry Subscale but not the Behaviour Subscale (Hepburn et al 1994). Patients with reduced awareness are more likely to experience severe hypoglycaemia (Gold et al., 1994) therefore increasing the likelihood of fear of hypoglycaemia.

Reduced ability to monitor blood glucose may also increase fear of hypoglycaemia. (Cox, Kiernan, Schroeder, & Cowley, 1998) compared sight-impaired (reduced ability to read blood testing machines) to non-impaired patients with diabetes and found that those with visual complications were more worried about hypoglycaemia.

Only one study has investigated the effect of the duration of diabetes. (Gafvels, Lithner, & Borjeson, 1993) found that although patients with a longer duration of diabetes were more concerned about chronic complications, they were less concerned about their diabetes management.

Different types of diabetes medications have different risks of hypoglycaemia, but as many studies only include participants that are on insulin, the effect of different diabetes medications has not been directly addressed.

1.2.2. Gender

Females tend to score higher on both behaviour and worry subscales and this is in line with other measures of anxiety where women generally score higher.

(Gafvels et al., 1993) questioned 448 patients in Northern Sweden who took insulin and found that men were less worried than women about hypoglycaemia and the risk of future complications.

1.2.3. Ethnicity

Studies have investigated fear of hypoglycaemia in European (e.g. Irvine, Cox, & Gonder Frederick, 1994; Costea et al., 1993), North American (e.g. Hepburn, Deary, MacLeod, & Frier, 1994; Irvine et al., 1994), and Asian populations (Shiu & Wong, 2000). However, there have been no published studies of fear of hypoglycaemia in New Zealand or Australia, and no study has directly attempted to investigate fear of hypoglycaemia across ethnic groups.

1.2.4. Age

Fear of hypoglycaemia has been found in children, and adolescents (Green, Wysocki, & Reineck, 1990) as well as adults. There is some evidence that there may be some differences depending on age but this has not been clearly established. (Eaton, Mengel, Mengel, & Larson, 1992) did not measure fear of hypoglycaemia but found better metabolic control improved with age in patients with IDDM.

1.2.5. Anxiety and depression

Anxiety and depression have been found to be associated with an increase in fear of hypoglycaemia (Costea et al., 1993; A. Irvine et al., 1992). Polonsky et al., (1992) found higher HFS scores were associated with higher trait anxiety and fear on other measures in both type 1 and type 2.

1.2.6. Personality

Personality is likely to affect the measurement of fear of hypoglycaemia. Hepburn et al., (1994) in a large study of patients with IDDM found that personality accounted for more variance in HFS scores than any other factor. Hepburn et al. suggested that personality affects self-report and the assessment of symptoms by others. Neuroticism was found to be the biggest influence on the worry subscale of the HFS. Coping styles have also been found to affect metabolic control (Macrodimitris & Endler, 2001; Peyrot, McMurray, & Kruger, 1999). White, Tata, & Burns, (1996) found that there was a relationship between poor metabolic control and, passive dependent coping style in 90 IDDM patients.

1.2.7. Psychosocial factors:

Peyrot et al., (1999) compared personality, psychosocial resources and glycaemic control in patients with type 1 and type 2 diabetes. They found improved glycaemic control in people with stable psychosocial resources (e.g. higher education, married, positive coping styles) whereas stress was associated with poorer metabolic control.

1.2.8. Link between fear of hypoglycaemia and metabolic control

Studies that directly ask participants if they fear hypoglycaemia have found that fear of hypoglycaemia decreases people's desire to improve metabolic control. Ramchandani et al., (2000) found that a fear of hypoglycaemia (self-reported) was a barrier to improving metabolic control in college students in the United States. (They also found that a fear of *hyper*glycaemia improved diabetes control.)

Thompson et al., (1996) concluded from a survey of people with diabetes that fear of hypoglycaemia was a significant impediment to achieving better glycaemic control in adults with type 2 diabetes. Liakopoulou, Korvessi, & Dacou-Voutetakis, (1992) found that HbA_{1c} (a measure of metabolic control) was significantly higher in adolescents who worried more about their diabetes.

However, this has not been clearly shown in studies of fear of hypoglycaemia using HbA_{1c} as a measure of metabolic control. Some authors have pointed out that HbA_{1c} masks the daily fluctuations in blood glucose levels (Irvine et al., 1994). This variability may be important in determining the risks of future hypoglycaemia. However, HbA_{1c} remains the most commonly used and accurate measure of overall metabolic control (American Diabetes Association, 2000).

1.2.9. Appropriate versus inappropriate fear

It seems likely that excessive fear in some people is likely to compromise their metabolic control and in the longer term increase the risk of diabetes related complications; conversely, it also seems possible that a lack of fear could be harmful. Cox et al., (1987) suggest that for patients at greater risk of hypoglycaemia, particularly those with impaired awareness, a certain degree of fear may be a motivating factor to avoid the potentially life threatening condition of severe hypoglycaemia. Cox et al. further suggest that there is a normal range of fear of hypoglycaemia and that both elevated and suppressed levels may compromise good metabolic control.

Irvine et al., (1994) introduced the concept of adaptive and maladaptive fear according to the risk of future hypoglycaemia. When the risk of hypoglycaemia is

high then a certain amount of fear is adaptive, whereas when the risk is low the same level of fear would be maladaptive. Similarly when the risk of hypoglycaemia is low (e.g. when blood glucose is high) then no fear is adaptive, however, a high fear is maladaptive. Figure 1.1 (adapted from Irvine et al., 1994) summarises the relationship between the risk of hypoglycaemia and fear of hypoglycaemia.

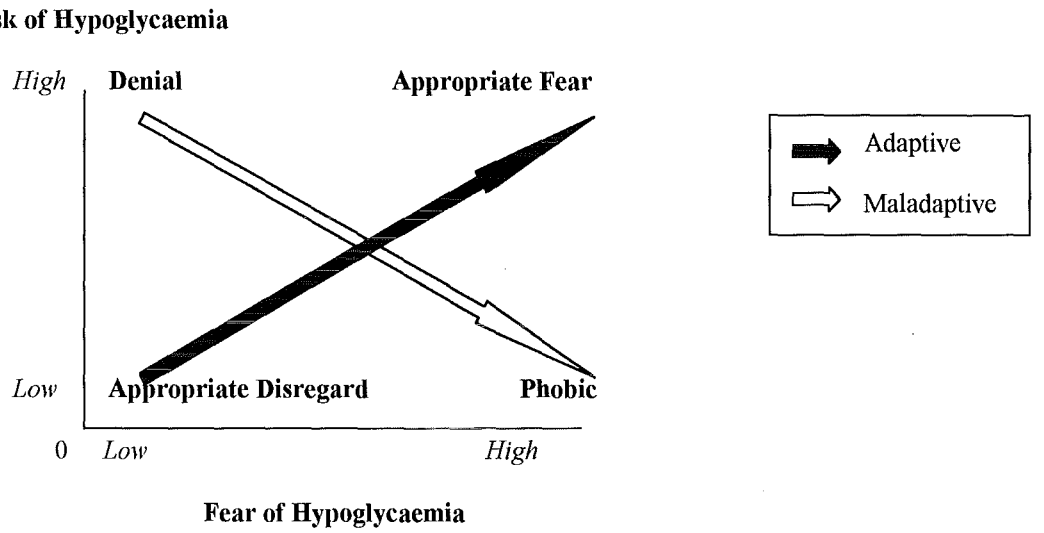


Figure 1.1. Adaptive and maladaptive fear of hypoglycaemia as a function of the risk of hypoglycaemia (adapted from Irvine et al., 1994, p152).

A simple linear model which conceptualises fear of hypoglycaemia solely as a result of previous exposure of a feared stimulus resulting in avoidance behaviour which in turn leads to poor metabolic control does not provide an adequate picture of the phenomenon. This has led some researchers to conclude that at present

most of the variance in fear of hypoglycaemia models remains unexplained (Hepburn et al., 1994; Irvine et al., 1994).

1.3. Psychological aspects of diabetes

There are disproportionately high rates of psychological disorders in patients with diabetes when compared to the general population (Rubin & Peyrot, 2001). Anxiety and depression are the two most common disorders in patients with diabetes (Gavard, Lustman, & Clouse, 1993). A study of patients with type 1 or type 2 diabetes, 28% reported moderate to severe levels of depression, anxiety, or both at the time of the interview (Lloyd, Dyer, & Barnett, 2000). However, another study found that although rates of anxiety and depression overall are higher in a diabetic population, they may not differ in the proportion who fall in the pathological range (Smari & Valtysdottir, 1997). Both depression and anxiety have been found to be greater in patients who are female, have more diabetes-related complications, higher HbA_{1c}, are unmarried, and are less educationed (Peyrot & Rubin, 1997).

1.3.1. Anxiety

Rubin & Peyrot, (2001) suggests that patients with diabetes may experience higher levels of anxiety than the general population because they often have greater sources of fear such as hypoglycaemia, diabetes complications, regular blood testing, and insulin injections.

Anxiety has been found to negatively affect metabolic control in adults (Niemcryk, Speers, Travis, & Gary, 1990) and adolescents (Rempala, 1999). However, Rempala, found that anxiety was related to better metabolic control in pre-adolescents. Wiebe, Alderfer, Palmer, Lindsay, & et al., (1994) in a small study of adolescents with type 1 diabetes found that anxiety was related to poorer metabolic control, and anxious adolescents tended to attribute physiological sensations to hypoglycaemia more often than their less anxious peers. Liakopoulou et al., (1992) found that anxiety did not affect metabolic control in 40 Greek adolescents. This study had only a small sample, however, HbA_{1c} was significantly higher in those that worried more about their diabetes.

Symptoms of anxiety, which include panic symptoms, are sometimes similar to that of hypoglycaemia. Steel, Masterton, Patrick, & McGuire, (1989) reported two case studies in which patients mistook hyperventilation for hypoglycaemia, leading to unnecessary treatment and high blood glucose levels. Conversely, panic attacks are not brought on by hypoglycaemia (Schweizer, Winokur, & Rickels, 1986).

1.3.2. Depression

Estimates of lifetime prevalence rates of major depression in patients with type 1 and type 2 diabetes range between 14.4% and 32.5% (de Groot, Jacobson, Samson, & Welch, 1999). A meta analysis of 27 studies found a significant association between depression and diabetes complications (de Groot, Anderson, Freedland, Clouse, & Lustman, 2001).

Depression, even at sub clinical levels may worsen metabolic control, possibly by decreased self-care (Van Tilburg et al., 2001) or at a physiological level by hormone dysregulation (Lustman, Griffith, & Clouse, 1998). Diabetes and depression share some symptomatology such as fatigue, changes in sleep, and appetite (Rubin & Peyrot, 2001). Treatment of depression has been shown to improve metabolic control (Lustman et al, 1998). The relationship between depression and diabetes, poor metabolic control and increased complications remains unclear, and the relationship may be different for different individuals, and type of diabetes (de Groot et al., 2001). One study (Eaton, Pratt, Armenian, Ford, & Gallo, 1996) suggests that depression is an increased risk factor for the onset of type 2 diabetes.

1.4. This Study

This study makes and tests predictions of relationships between different variables and fear of hypoglycaemia. The factors investigated in this study and the predicted effects on fear of hypoglycaemia are shown in Figure 1.2.

Factors in the top left box are predicted to have a positive relationship with fear of hypoglycaemia. There have been many studies that have found that patients with a fear of hypoglycaemia are more likely to have previously experienced hypoglycaemia. This is consistent with fear of hypoglycaemia as phobic avoidance of a feared situation. The more severe the past experience the more likely fear of hypoglycaemia is to develop. Patients with type 1 diabetes are also predicted to be more likely to develop fear of hypoglycaemia as they are more

susceptible to hypoglycaemia than patients with type 2 diabetes, even when using insulin. Type of medication has not been studied previously. It is predicted that there will be a hierarchy of fear of hypoglycaemia due to medication with the highest fear of hypoglycaemia in those on insulin, followed by sulphonylureas, metformin, and finally those that are not on diabetes medication (diet controlled). This hierarchy is based on the action of the various medications and the corresponding probability of hypoglycaemia.

Anxiety and depression have been found to be associated with higher fear of hypoglycaemia in previous studies and this is predicted in this study also. However, it should be noted that anxiety and depression might also directly affect metabolic control due to factors other than fear of hypoglycaemia such as compliance and motivation. Females are expected have greater fear of hypoglycaemia as this trend is common to most anxiety traits.

Living alone has not been studied previously but it is predicted that this may increase fear of hypoglycaemia as there is a greater risk of developing severe hypoglycaemia if there is no one to assist with or identify early signs of hypoglycaemia.

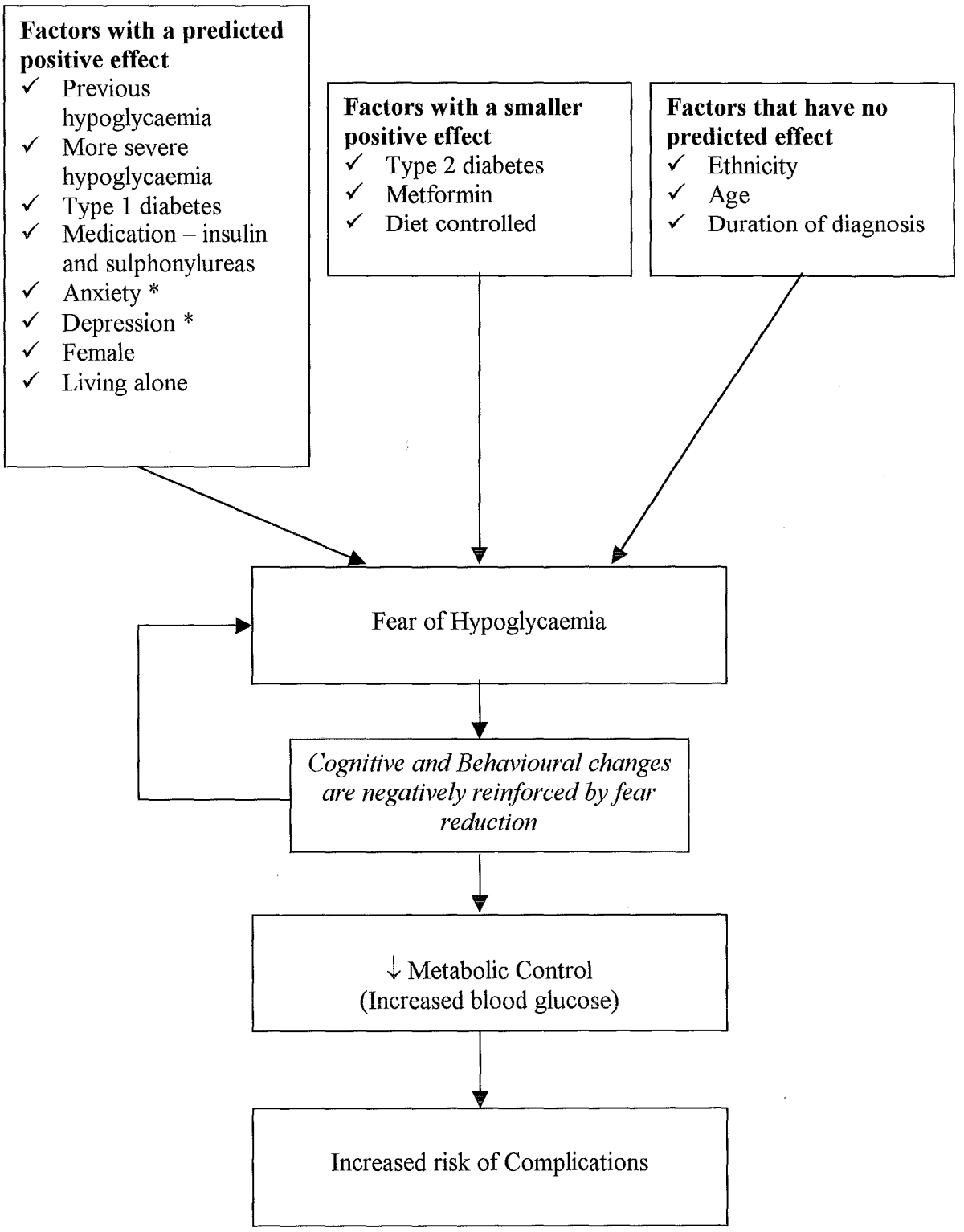
The middle box identifies factors that are predicted to be positively, but less strongly related to fear of hypoglycaemia. Patients with type 2 diabetes are expected to experience less fear of hypoglycaemia than type 1 diabetes. Some patients taking metformin, an oral diabetic medication that does not have hypoglycaemic action, and those that are diet controlled are still predicted to

experience some level of fear of hypoglycaemia due to misconceptions about diabetes.

The box on the right side of Figure 1.2 contains factors that either have not been investigated previously or for which there are unclear or conflicting results. Ethnicity has not been included in other studies; however, this may be useful to consider in the New Zealand context, particularly as more Maori and Pacific Island People develop diabetes. Whether age and duration of diagnosis affect fear of hypoglycaemia has not been established yet.

Once a fear of hypoglycaemia has been established it is likely that it will induce behavioural changes (e.g. avoiding hypoglycaemia by keeping blood glucose high, testing more frequently then required) and cognitive changes (e.g. increased worry about hypoglycaemia). These behavioural changes and cognitive processes are both negatively reinforced by short-term reduction in fear, and also serve to maintain fear levels. In some patients, but not necessarily all, the avoidance behaviour may involve compromising metabolic control by keeping blood glucose levels high. This in turn places the patient at a higher risk of developing diabetes related complications.

As stated by (Irvine et al., 1994) a simple linear model is insufficient to explain all the variance in fear of hypoglycaemia and the model presented here is not expected to cover the complete range of possibilities.



* These factors are predicted to affect fear directly but may also have a direct effect on metabolic control due to factors such as compliance and motivation issues.

Figure 1.2. Predicted factors that affect fear of hypoglycaemia and metabolic control.

In summary the aims of this study are

- To identify the prevalence of fear of hypoglycaemia in the population attending the Christchurch Diabetes Centre.
- To investigate the relationships between fear of hypoglycaemia and the following variables: type of diabetes, previous hypoglycaemia experience, metabolic control, diabetes medication, and demographic variables.
- To determine the level of depression and anxiety and investigate the relationship they have with fear of hypoglycaemia and metabolic control.

2. METHODS

2.1 Participants

Participants in this study were all diagnosed with diabetes mellitus either type 1 or type 2 and were patients attending the Christchurch Diabetes Centre. This Centre is a tertiary referral clinic for greater Christchurch and draws patients from newly diagnosed cases in the community, long-standing cases with complications, and hospital admissions. Therefore, the patients attending tend to have type 1 diabetes, or more advanced and complicated type 2 diabetes that is unable to be managed solely by a general practitioner. The age range of patients seen at the Diabetes Centre is from approximately age 12 to 13 years upwards.

Following approval from the Canterbury Ethics Committee, all patients booked to attend a clinic appointment with a physician at the Christchurch Diabetes Centre between 23 November 2000 and 26 January 2001 were screened for eligibility to participate in the study. All patients were eligible unless they met the following exclusion criteria:

1. A request by the patient not to be involved in research projects (recorded in their diabetes clinic file).
2. Reduced cognitive capacity such that that person could not complete the questionnaires. This was judged by the researcher by reading clinic files (examples of exclusion included a history of strokes resulting in significant cognitive deficits, and intellectual disability).

The researcher reviewing patient files carried out initial screening. Names of patients who were eligible to participate were then forwarded to the appropriate physician for confirmation of eligibility.

2.2 Procedure

All clinic attendees who met the criteria were sent a letter and an information sheet (see Appendix A) at least one week before their appointment informing them about the study and inviting them to participate during their clinic appointment. Patients were then approached in person when they attended the clinic for their appointment. Those who agreed to participate were asked to complete a consent form (see Appendix A). Participants were also asked to indicate whether they would like to be sent their individual results, whether they would like their general practitioner to be sent their results, and whether they would like to receive a summary of the results when the study was completed.

Participants then completed questions about themselves and their diabetes history and two questionnaires described below. The participants were required to answer all questions themselves but assistance from others such as the researcher or relatives was acceptable where required. A Maori Health Worker and Samoan Registered Nurse were available if further assistance was required. Enlarged forms were available for participants who were sight impaired.

2.3 Measures

Copies of the demographic and diabetes history questions and the two questionnaires used in the study are in Appendix B.

2.3.1 Demographic and diabetes history questions

These questions were designed to gather information regarding the participant's ethnicity and living situation. Information regarding the participant's diabetes history and management was also requested along with whether they were currently taking medications for anxiety and depression.

The information from these questions and patient records, was used to group participants into the following categories according to diabetes treatment:

- **D** - all participants not on medication - diet controlled
- **M** - Participants on tablets with no hypoglycaemic action (metformin only).
- **S** - Participants on tablets with hypoglycaemic action (sulphonylureas alone or sulphonylureas & metformin).
- **I** - Participants on insulin (insulin alone, insulin & metformin, insulin & sulphonylureas, or insulin, metformin & sulphonylureas).

Participants in categories D and M would not experience hypoglycaemia and were additionally coded as "cannot hypo[1]" whereas those in categories S and I could have hypoglycaemic episodes and were therefore coded as "can hypo".

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1. "hypo" is a commonly used term to describe a hypoglycaemic episode.

2.3.2 Hypoglycaemia Fear Survey (HFS)

The Hypoglycaemia Fear Survey (HFS) is a 23 item, Likert scale, paper and pencil measure that is easily completed in five to ten minutes. It was developed as a clinical and research tool to measure the degree to which people with diabetes fear hypoglycaemia (Cox et al., 1987). The HFS has been validated in several overseas studies for use with adults (Irvine et al., 1994) and children (Green et al., 1990) and has been found to be able to identify individuals at risk of poor metabolic control due to their beliefs and behaviours.

The HFS consists of two subscales, Behaviour and Worry. The Behaviour subscale (10 items) captures what people do to avoid low blood sugar levels and how often they do it. Some of these behaviours are important for management of hypoglycaemic episodes (such as carrying fast-acting sugar at all times) but many others are not necessary for management of hypoglycaemia and serve as avoidance tactics that often result in higher blood glucose levels. As such, a low score on this subscale may indicate a healthy and safe management technique, and higher scores indicate that the individual may be managing less well. Conversely, a low behaviour score may indicate an increased risk for a hypoglycaemic episode as they are neglecting to monitor or plan for hypoglycaemia.

The Worry subscale (13 items) measures cognitive factors that may influence how people manage their blood sugar levels. Very low levels may place an individual at risk of hypoglycaemia, as they may be unmotivated to manage their diabetes well. Moderate levels are probably useful for maintaining motivation for keeping blood glucose at the appropriate level. High scores above 40 may indicate that the

individual is fearful of hypoglycaemia and may avoid it by keeping blood glucose higher than necessary.

The version of the HFS used in this study was modified with the consent of the developer of the scale, Daniel Cox. The North American term for hypoglycaemia (reaction) was substituted with the common term used in New Zealand (hypo).

2.3.3 The Hospital Anxiety and Depression Scale (HADS)

The Hospital Anxiety and Depression Scale (HADS) is a widely used measure of anxiety and depression for use in medical settings and has been designed to avoid items that may be endorsed due to physical rather than psychological symptoms (Zigmond & Snaith, 1983). The HADS has been shown to be an appropriate questionnaire for use with patients with diabetes in clinic settings (Lloyd et al., 2000). It is a 14 item, Likert scale questionnaire that is rapidly completed and is acceptable to adolescent (White, Leach, Sims, Atkinson, & Cottrell, 1999) and adult medical populations. It has well validated psychometric properties (Herrmann, 1997; Johnston, Pollard, & Hennessey, 2000). The HADS can be divided into two subscales to give measures of anxiety (7 items), and depression (7 items). Each of these subscales can be divided into three levels of severity (0-7 normal, 8-10 possible anxiety/depression, and 11-21 probable anxiety/depression).

2.3.4 Glycosylated Haemoglobin (HbA_{1c})

HbA_{1c} is a recommended index of glycaemic control and gives an indication of control over the previous six to eight weeks (American Diabetes Association, 2000). All patients attending clinic appointments routinely have HbA_{1c} levels

measured by blood test prior to the clinic appointment or by capillary test at the clinic. HbA_{1c} was also categorised as good, fair and poor to reflect the level of control and the corresponding risks of damage due to hyperglycaemia (Table 2.1). Although the demarcations of this categorisation are relatively arbitrary, they are used in clinical settings.

Table 2.1. Metabolic control categories for HbA_{1c} levels.

HbA_{1c} (mmL^{-1})	**Category**
< 7	Good
7.0 – 9.0	Fair
>9.0	Poor

2.4 Statistical Analysis

Data was entered into a database in Microsoft Excel and then transferred to SPSS for analysis. Analysis included descriptive statistics, correlational analysis, Chi-square analysis, analysis of variance (ANOVA), and regression analysis. All reported significance values are 2 tailed.

3. RESULTS

3.1. Response rate

Over the sampling period 316 patients attending the Diabetes Centre were approached to participate in the study. Of these, 281 (89%) completed the consent form, and 272 (86%) completed all questionnaires. The response rate of 86% is very favourable compared to previous studies at the Diabetes Centre where approximately 50% responded.

3.2. Descriptive statistics

3.2.1. Ethnicity

A breakdown of ethnic identity is shown in Table 3.1. The majority of participants identified as Pakeha/New Zealand European with only 4% identifying as Maori and 2% as Pacific Island people. Twenty participants (7%) declined to answer this question.

Table 3.1. Ethnicity of participants

Ethnic identity	**Frequency**	**Percent**
Pakeha/New Zealand European	229	91
Maori	8	3
Maori and Pakeha	3	1
Asian	5	2
Pacific Island	5	2
Other	4	1
Total	252	100

There were proportionately more Maori with type 2 than type 1 diabetes (Maori made up 5% of type 2 but only 1.5% of type 1). Similarly, Pacific Island people made up 4 % of those with type 2 but none (0%) had a type 1diagnosis. Sample sizes were too small to test whether these differences were significant.

3.2.2. Gender, age and diagnosis

There was a fairly even sex ratio, however slightly more males (52%) than females (48%) completed the questionnaires. There were no differences in the sex of type 1 and type 2 participants (males made up 53% and 52% of type 1 and type 2 participants respectively and, females made up 47% and 48%).

The average age of participants was 48 years (SD=19, range 12 to 86 years). Forty three percent of participants had a diagnosis of Type 1 diabetes while the remaining 57% had Type 2. As age of onset of type 1 diabetes is generally younger than for type 2 diabetes, this difference is reflected in the ages of the respondents in the study. The average age for participants with type 1 diabetes was 34 years (SD =17, n=116) and for type 2 was 59 years (SD=13, n=155). Figure 3.1 shows the distribution of ages for each diagnosis and confirms that age and diagnosis are correlated and not independent variables. Participants with type 1 diabetes were likely to have been diagnosed for a longer time (M = 14 years, SD = 13, range 0.2 - 52 years) than those with type 2 (M = 9 years, SD = 8, range 0.1 - 54 years). An ANOVA found this to be a significant difference ($F[1,270] = 12.06$, $p=.001$).

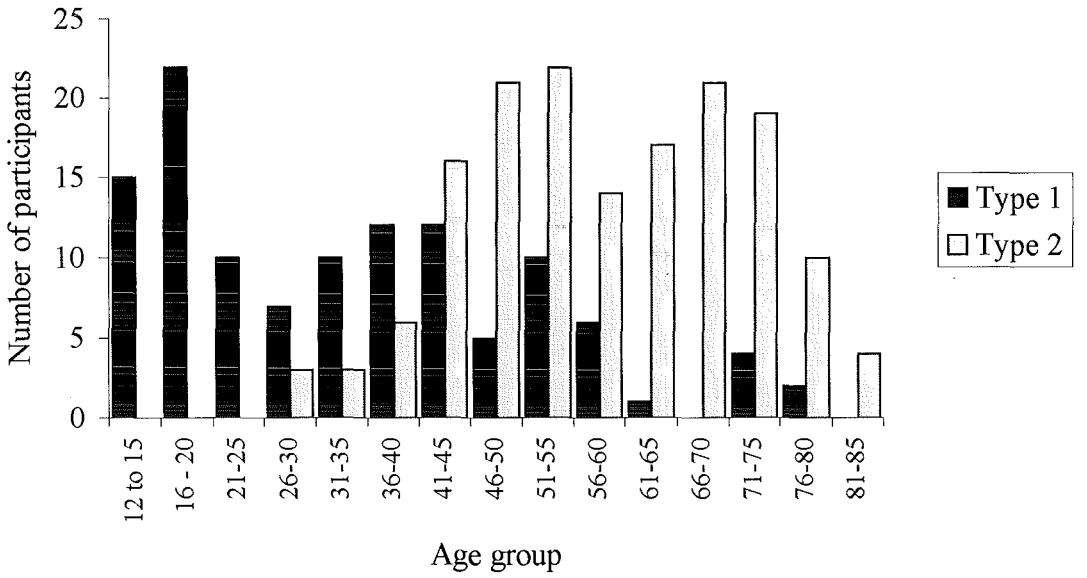

Figure 3.1. Age distribution of participants with type 1 diabetes compared to participants with type 2 diabetes.

3.2.3. Diabetes medication

The combinations of different diabetes medications taken by participants can be seen in Table 3.2. Many of the participants were prescribed more than one type of diabetes medication, with some participants taking up to three different types. The majority (78%) of participants were taking insulin and 16% took a sulphonylurea (has hypoglycaemic action). Over all, 89% of participants were taking medication that can cause hypoglycaemia. The remaining 11% were either taking metformin or were controlled by diet and lifestyle factors alone and should not be physiologically able to experience hypoglycaemia.

As expected there were large differences in treatment regimes for type 1 and type 2 participants. All participants with type 1 were on insulin compared to 61% of those with type 2.

Table 3.2. The percentage of participants with type 1, type 2 diabetes, and both types combined that take different diabetes medications.

Diabetes Medication	**Type 1(%)**	**Type 2 (%)**	**Type 1 & 2 (%)**
Insulin only	97	40	64
Insulin and sulphonylureas	0	1	1
Insulin, sulphonylureas and metformin	1	5	10
Insulin and metformin	2	15	3
Sulphonylureas only	0	7.5	4
Sulphonylureas and metformin	0	13	7
Metformin only	0	13.5	8
Diet only	0	5	3
Totals	100	100	100

More than half of the participants had had a change in their medication in the previous twelve months (Figure.3.2). The range in time since medication was last changed was from 1 month up to 10 years (120 months) with the average being 11 months (SD=15, N = 253). There was no difference between type 1 (M = 11 months) and type 2 participants (M = 10 months).

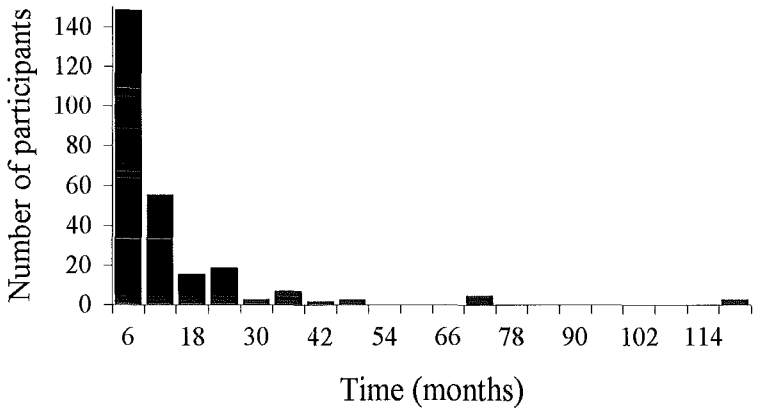

Figure 3.2. Time elapsed since the last time medication was changed for all participants.

3.2.4. Previous experience of hypoglycaemia

Table 3.3. shows that two thirds (67%) of all participants had taken measures to avoid hypoglycaemia. Most (81%) had previously experienced hypoglycaemic symptoms and 38% reported that they had required help from others to manage a hypoglycaemic episode.

Table 3.3. Previous experience of hypoglycaemia of participant according to type of diabetes.

	Type 1 (%)	**Type 2 (%)**	**Type 1 & 2 (%)**
Prevent hypoglycaemia	94	47	67
Experienced hypoglycaemia	96	71	81
Help for hypoglycaemia	65	17	38

Significantly more participants with type 1 diabetes had acted to prevent hypoglycaemia than those with type 2 (Pearson Chi-square, $\chi^2[1] = 66.86$, $p<.001$). Participants with type 1 diabetes were also more likely to have previously experienced hypoglycaemia ($\chi^2[1] = 27.68$, $p<.001$), and to have required assistance to treat hypoglycaemia ($\chi^2[1] = 63.07$, $p<.001$).

3.2.5. Metabolic control

Glycated haemoglobin (HbA_{1c}) was used to assess metabolic control over the previous two months. The mean HbA_{1c} of all participants was 8.3 (SD = 1.6, range 5.1 - 15.3). The mean for type 1 was 8.7 (SD = 1.8, range 5.5 - 15.3), which was higher than the mean for type 2 of 8.0 (SD = 1.5, range 5.1 - 12.1). Although this difference was statistically significant ($F[1,269], = 9.43$, $p = <.01$), it is unlikely to be a clinically significant difference.

Table 3.4 shows that metabolic control in the sampled population was fairly evenly divided between good, fair and poor categories.

Table 3.4. The percentage of participants with good, fair and poor metabolic control for type 1, type 2 and both types combined.

Metabolic Control	**HbA_{1c} Range**	**Type 1**	**Type 2**	**Type 1 & 2**
Good	<7	25	39	32
Moderate	7.0-9.0	35.5	36	39
Poor	<9.0	42.5	25	29

3.2.6. Medication for anxiety and/or depression

The percentage of participants taking medication for depression and/or anxiety was 11%. Slightly more participants with type 2 diabetes (15%) were on medication for depression or anxiety than those with type 1 (4%). A Pearson Chi-square analysis found this to be a significant difference ($\chi^2[1] = 8.57$, $p<.01$).

3.2.7 Living alone, blood testing machine

Overall 19% of participants lived alone. There was no significant difference between the percentage of participants with type 1 (14%) and type 2 (22%) who lived alone.

Almost all those sampled (97%) had a blood-glucose testing machine at home.

3.3. The Hospital Anxiety and Depression Scale

The mean score of the HADS Anxiety Subscale for all participants was 6.4 (SD=3.9) and ranged from 0 to 18 out of a possible 21. The mean score for the Depression Subscale was 3.7 (SD= 3.2) with a range from 0 to 15 out of a possible total of 21.

Figure 3.3 shows that the majority of participants scored in the normal range of between 0 and 7 for both the Anxiety and Depression Subscales. In the Anxiety Subscale 27% of participants scored in the moderate range indicating possible anxiety and 16% fell in the higher range indicating probable anxiety. Fewer participants scored in the possible and probable ranges for the Depression Subscale (16% and 3% respectively).

There was a similar distribution of HADS scores when participants with type 1 and type 2 are considered separately (Figure 3.4). There was no difference between the mean scores for anxiety (type 1 M = 6.13, SD = 3.65; type 2 M = 6.56, SD = 4.15; F[1,265] = .773, NS) or depression (type 1 M = 3.32, SD -= 3.10; type 2 M = 4.03, SD = 3.28; F[1,265] = 3.28, NS)

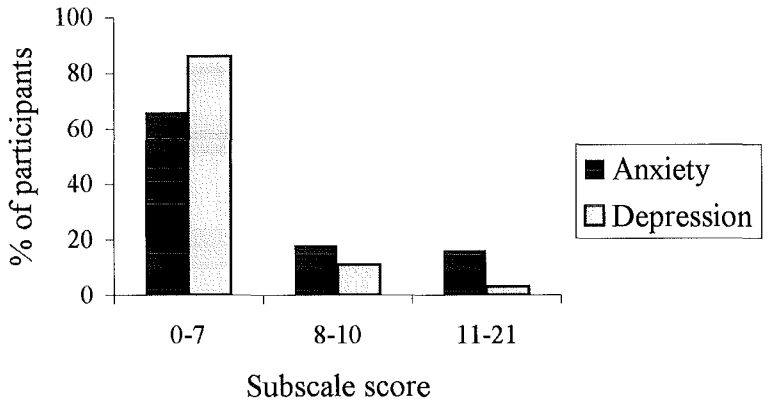

Figure 3.3. Distribution of scores for the Anxiety and Depression Subscales of the HADS for all participants. Scores 0-7 are normal, 8-10 are possible anxiety/depression, 11-21 probable anxiety/depression.

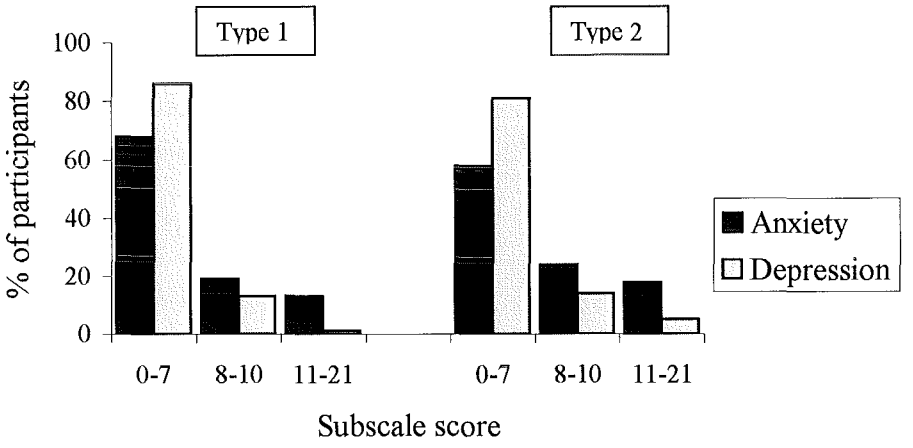

Figure 3.4. Distribution of scores for the Anxiety and Depression Subscales for the HADS for type 1 and type 2 diabetes separately. Scores of 0-7 are normal, 8-10 are possible anxiety/depression, 11-21 are probable anxiety/depression.

The correlations between the anxiety and depression subscales can be seen in Table 3.5. Depression and anxiety were positively correlated (Pearson correlation, $r = 0.616$, $p<0.001$).

There was no relationship of either anxiety or depression with age, or years since diagnosis. There was a modest positive correlation between anxiety and HbA_{1c} in participants with type 1 diabetes.

Table 3.5. Results of Pearson correlation analysis for the HADS scores and HbA_{1c}, age and years since diagnosis.

	HADS Anxiety			**HADS Depression**		
	Type 1	**Type 2**	**Type 1 & 2**	**Type 1**	**Type 2**	**Type 1&2**
HADS Anxiety						
Pearson Correlation	1.000	1.000	1.000	**.605****	**.616****	**.616****
p value				.000	.000	.000
N	114	153	272	114	153	269
HADS Depression						
Pearson Correlation	**.605****	**.616****	**.616****	1.000	1.000	1.000
p value	.000	.000	.000			
N	114	153	269	114	156	272
HbA_{1c}						
Pearson Correlation	**.244****	.010	.095	.158	-.001	.041
p value	.009	.906	.122	.095	.986	.500
N	113	153	268	113	153	268
Age						
Pearson Correlation	-.039	-.119	-.025	.154	-.108	.088
p value	.679	.144	.679	.101	.183	.149
N	114	153	269	114	153	269
Years since diagnosis						
Pearson Correlation	-.060	.019	-.018	.038	.025	.025
p value	.527	.816	.771	.686	.756	.681
N	114	153	269	114	153	269

** level of significance $p < .001$

As shown in Table 3.6 the mean for females was significantly higher than the mean score for males in the anxiety subscale but there was no significant difference for depression. No differences were found for either subscale between type 1 and type 2 diabetes, or type of medication. Those who were taking medication for anxiety and or depression had significantly higher mean scores on both subscales.

Mean anxiety was higher in those that had experienced hypoglycaemia in the past but not depression. Those who had required help for hypoglycaemia did not show any significant differences for anxiety or depression.

There were no significant mean differences for anxiety or depression in participants who were living alone compared to those who were not.

Table 3.6. The relationship between the HADS scores and sex, depression medication, and previous experience of hypoglycaemia.

	HADS Anxiety			**HADS Depression**		
	Type 1	**Type 2**	**Type 1 & 2**	**Type 1**	**Type 2**	**Type 1&2**
Sex						
Female mean	6.96	7.64	7.38	3.20	4.45	3.95
SD	3.92	4.08	4.02	3.14	3.27	3.28
N	55	74	130	55	74	130
Male mean	5.25	5.54	5.42	3.37	3.65	3.51
SD	3.17	3.97	3.63	3.04	3.25	3.15
N	59	79	139	59	153	139
F	**6.60**	**10.317**	**17.69**	.089	2.30	1.28
p value	**.012**	**.002**	**.000**	.766	.131	.259
Depression medication						
"Yes" mean	9.80	9.22	9.32	7.20	7.09	7.11
SD	4.44	3.78	3.82	3.90	3.23	3.28
N	5	23	28	5	23	28
"No" mean	5.91	6.08	6.03	3.11	3.49	3.33
SD	3.53	4.04	3.81	2.93	2.98	2.97
N	109	130	241	109	130	241
F	**5.703**	**11.97**	**18.71**	**9.07**	**27.66**	**39.57**
p value	**.019**	**.001**	**.000**	**.003**	**.000**	**.000**
Prevent hypoglycaemia						
"Yes" mean	6.08	6.85	6.42	3.26	4.14	3.63
SD	3.58	4.38	3.93	3.09	3.47	3.38
N	107	72	181	107	72	181
"No" mean	6.00	6.30	6.27	3.71	3.94	3.92
SD	4.69	3.93	3.97	2.98	3.11	3.09
N	7	81	88	7	81	88
F	.003	.672	.082	.141	.142	.483
p value	.953	.414	.774	.708	.707	.488
Previous hypoglycaemia						
"Yes" mean	6.25	6.98	6.63	3.33	4.26	3.80
SD	3.61	4.35	4.00	3.11	3.34	3.26
N	109	108	219	109	108	219
"No" mean	2.4	5.53	5.22	2.40	3.49	3.38
SD	2.19	3.45	3.46	2.07	3.09	3.01
N	5	45	50	5	45	50
F	**5.57**	**3.95**	**5.34**	.436	1.77	.706
p value	**.020**	**.049**	**.022**	.511	.186	.401

Table continued on next page.

Table 3.6 (continued)

	HADS Anxiety			HADS Depression		
	Type 1	Type 2	Type 1 & 2	Type 1	Type 2	Type 1&2
Help with hypoglycaemia						
"Yes" mean	6.51	7.96	6.95	3.68	4.70	4.00
SD	3.69	4.74	4.04	3.20	3.72	3.38
N	74	27	102	74	27	102
"No" mean	5.28	6.30	6.05	2.57	3.92	3.58
SD	3.43	3.95	3.86	2.72	3.16	3.10
N	40	125	163	40	125	163
F	3.07	2.76	3.31	3.40	1.40	1.09
p value	.083	.066	.070	.068	.248	.298

3.4. The Fear of Hypoglycaemia Scale

The Behaviour Subscale mean score for all participants was 13.4 (SD = 8.3, N = 272) and ranged from 0 to 38 out of a possible total of 40. The distribution of scores is negatively skewed and is shown in Figure 3.5.

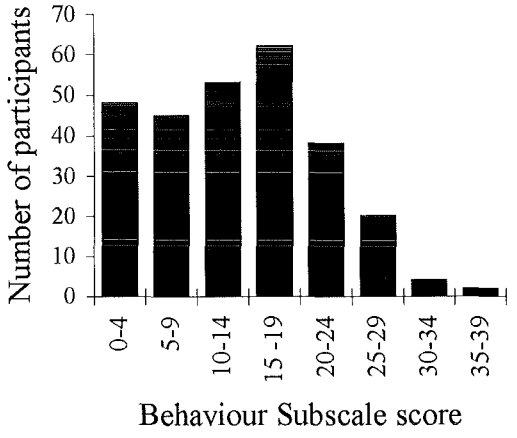

Figure 3.5. Distribution of scores for the Behaviour Subscale of the HFS for all participants.

The Worry Subscale mean score for all participants was 13.9 (SD = 12.9, N = 272) and ranged from 0 to 52 out of a possible 52. The distribution of scores is shown in Figure 3.6 and, like the behaviour subscale, is negatively skewed.

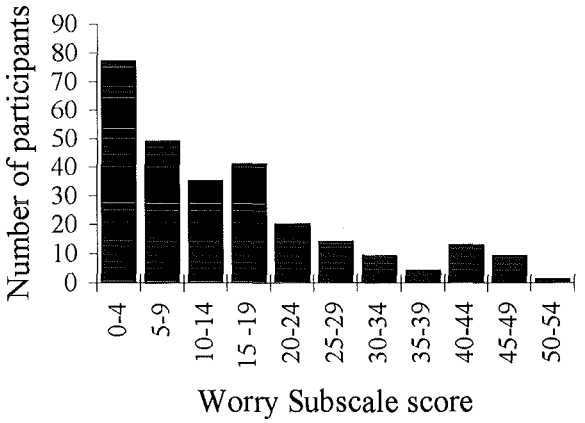

Figure 3.6. Distribution of scores for the Worry Subscale scores of the HFS for all participants.

The Total HFS Score is the sum of the Behaviour and Worry Subscales. The mean total HFS score was 27.3 (SD = 18.8, N=272) and ranged from 0 to 90 out of a possible total of 92. The distribution of scores is shown in Figure 3.7.

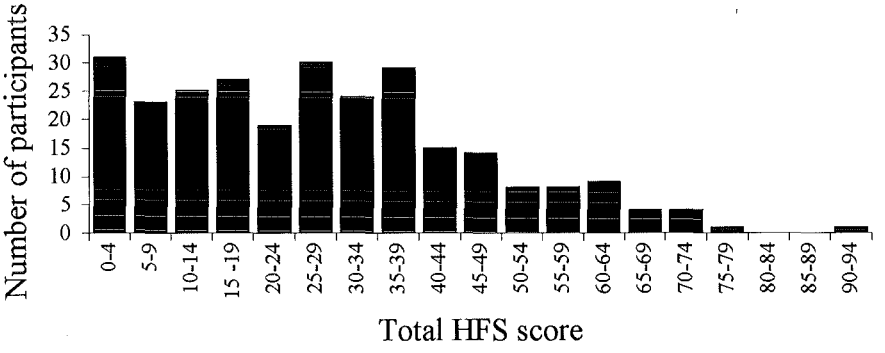

Figure 3.7. Distribution of the total HFS scores for all participants.

It was found that 16% of participants had a fear of hypoglycaemia as defined by a cut off score of 45 on the Total HFS score (approximately 1 standard deviation above the mean). Seventeen percent had little or no fear of hypoglycaemia as defined by a cut off of 10 on the Total HFS score (approximately 1 standard deviation below the mean). A Pearson Correlation analysis found a significant relationship between the behaviour and worry subscales ($r = 0.55$, $p<0.0001$) which indicates a link between worry associated with hypoglycaemia and behavioural management of diabetes.

The results of a 2-tailed Pearson Correlation between the scores from the HFS and the other continuous variables investigated are reported in Table 3.7.

Age was found to be significantly negatively correlated with all three scores from the HFS when diagnosis was combined. The Behaviour Subscale showed the largest correlation and suggests that older participants were less likely to avoid hypoglycaemia by changing their behaviour. However, there was no relationship between age and fear of hypoglycaemia when each diagnosis was considered separately.

Metabolic control (measured by HbA_{1c}) had a small positive correlation with all three measures of the HFS, indicating that poor metabolic control has some association with higher scores on this measure.

Table 3.7. Results of Pearson Correlation analysis for HFS and age, HbA_{1c}, anxiety, depression, duration of diagnosis and time since medications changed.

	Behaviour Subscale			**Worry Subscale**			**Total HFS**		
	Type 1	**Type 2**	**Type 1&2**	**Type 1**	**Type 2**	**Type 1&2**	**Type 1**	**Type 2**	**Type 1&2**
AGE									
Pearson Correlation	.124	.038	**-.307***	.119	-.156	**-.187***	.139	-.096	**-.263***
P value	.186	.641	.000	.204	.052	.002	.137	.232	.000
N	116	156	272	116	156	272	116	156	272
HbA_{1c}									
Pearson Correlation	.087	.065	**.162****	.166	.025	**.130***	.161	.044	**.160****
P value	.355	.424	.008	.077	.759	.033	.086	.583	.008
N	115	156	271	115	156	271	115	156	271
HADS Anxiety									
Pearson Correlation	**.337****	**.254****	**.201****	**.583****	**.610****	**.568****	**.576****	**.542****	**.480****
P value	.000	.002	.001	.000	.000	.000	.000	.000	.000
N	114	153	269	114	153	269	114	153	269
HADS Depression									
Pearson Correlation	**.253****	.102	.062	**.511****	**.321****	**.353****	**.488****	**.272****	**.271****
P value	.007	.211	.310	.000	.000	.000	.000	.001	.000
N	114	153	269	114	153	269	114	153	269
Years since diagnosis									
Pearson Correlation	.137	**.394****	**.321****	.179	.071	.169**	**.190***	**.213****	**.275****
P value	.144	.000	.000	.055	.382	.005	.041	.008	.000
N	116	156	272	116	156	272	116	156	272
Time since meds changed									
Pearson Correlation	.107	.157	.123	.181	.094	.138	.181	.132	.149
P value	.265	.063	253	.058	.266	253	.057	.118	253
N	111	141	252	111	141	252	111	141	252
Behaviour Subscale									
Pearson Correlation	1.000	1.000	1.000	**.445****	**.541****	**.553****	**.725****	**.798****	**.819****
P value				.000	.000	.000	.000	.000	.000
N	116	156	272	116	156	272	116	156	272
Worry Subscale									
Pearson Correlation	**.455****	**.541****	**.553****	1.000	1.000	1.000	**.939****	**.938****	**.931****
P value	.000	.000	.000				.000	.000	.000
N	116	156	272	116	156	272	116	156	272

** level of significance p<.001

Anxiety (HADS Anxiety Subscale) was found to have a modest positive correlation with the Behaviour Subscale of the HFS and a stronger positive correlation with the Worry Subscale and the HFS total score. This indicates an association between the level of anxiety and the cognitions of patients about hypoglycaemia in particular. Depression (HADS Depression Subscale) was found not to be correlated with the Behaviour Subscale but was moderately correlated with the Worry Subscale.

The time since diagnosis of diabetes had a small to moderate positive correlation with all three measures of the HFS indicating that fear of hypoglycaemia may increase with the duration of the illness. The time since medication was changed was not significantly correlated with any of the HFS scores.

Analysis if Variance (ANOVA) was used to compare the HFS scores for the discrete variables such as gender, ethnicity, diagnosis, medications and diabetes questionnaire items. Table 3.8 shows that females scored significantly higher than males when diagnosis was analysed separately and together for all three HFS scales with one exception; no significant difference was found between female and male means for the behaviour subscale in participants with type 1, although the trend was in the same direction.

Table 3.8. Comparison of HFS Scores for males and female participants

	Behaviour Subscale			**Worry Subscale**			**Total HFS Score**		
	Type 1	**Type 2**	**Type 1&2**	**Type 1**	**Type 2**	**Type 1&2**	**Type 1**	**Type 2**	**Type 1&2**
***Female* Mean**	19.79	11.46	15.05	20.14	14.11	16.71	39.93	25.57	31.75
SD	5.88	7.81	8.15	12.23	14.62	13.92	15.71	19.77	19.43
N	56	74	130	56	74	130	56	74	130
***Male* Mean**	17.77	7.51	11.85	15.73	8.17	11.37	33.50	15.68	23.21
SD	5.64	6.73	8.02	10.80	10.79	11.39	14.11	15.41	17.25
N	60	82	142	60	82	142	60	82	142
F	2.90	**11.50**	**10.58**	**4.25**	**8.43**	**12.08**	**5.39**	**12.26**	**14.75**
p value	.092	**.001**	**.001**	**.041**	**.004**	**.001**	**.022**	**.001**	**<.001**

Sample sizes were too small to enable statistical comparisons to be made between the scores of the HFS for different ethnic groups. However, the mean scores have been reported as they suggest that ethnicity may be an area for future research. New Zealanders of European decent had higher mean scores, particularly in the behaviour subscale, than Maori participants. Pacific Island participants also had a lower mean score than New Zealanders of European decent for the behaviour subscale and their mean worry score was almost half that of scores of New Zealand Europeans and Maori. Asian participants scored higher than any other ethnic group, however, one very high individual score is likely to have skewed the results.

Table 3.9. Comparison of HFS scores for different ethnic groups

	Behaviour Subscale	**Worry Subscale**	**Total HFS Score**
ETHNICITY			
NZ European Mean	**13.67**	**14.09**	**27.76**
SD	8.29	13.13	19.16
N=227			
Maori Mean	**7.88**	**13.37**	**21.25**
SD	4.19	14.21	14.06
N=8			
NZ European/Maori Mean	**7.33**	**7.33**	**14.67**
SD	11.02	5.03	12.22
N=3			
Pacific Island Mean	**10.00**	**7.80**	**17.80**
SD	6.2	6.57	11.32
N=5			
Asian Mean	**18.20**	**25.00**	**43.20**
SD	6.30	17.18	19.50
N=5			
Other Mean	**9.25**	**5.75**	**15.00**
SD	15.94	10.84	26.72
N=4			
Total Mean	**13.36**	**13.94**	**27.31**
SD	8.37	13.14	19.14
N=252			

Participants with type 1 diabetes scored significantly higher on all three HFS scales than those with type 2 diabetes (Table 3.10).

Table 3.10. Comparison of HFS scores between participants with type 1 and type 2 diabetes.

	Behaviour Subscale	**Worry Subscale**	**Total HFS Score**
DIAGNOSIS			
Type 1 Mean	18.74	17.86	36.60
SD	5.82	11.67	15.18
N=116			
Type 2 Mean	9.83	10.99	20.37
SD	7.50	13.05	18.24
N=156			
F	**124.564**	**20.180**	**60.622**
p value	**p<. 001**	**p<. 001**	**p<. 001**

There was a significant relationship between scores on the Behaviour Subscale and the Total HFS Score, and type of diabetes medication (Table 3.11).

Table 3.11. Comparison between HFS scores for different diabetes medications.

	Behaviour Subscale		**Worry Subscale**		**Total HFS Score**	
	Type 2	**Type 1&2**	**Type 2**	**Type 1&2**	**Type 2**	**Type 1&2**
MEDICATION						
I Mean	12.08	15.74	12.58	15.48	24.66	31.23
SD	7.41	7.36	12.77	12.43	17.74	17.39
N	95	211	95	211	95	211
A Mean	6.25	6.25	9.41	9.41	15.66	15.66
SD	5.44	5.44	13.35	13.35	16.65	16.65
N	32	32	32	32	32	32
B Mean	3.76	3.76	7.62	7.62	11.38	11.38
SD	4.72	4.72	13.13	13.13	16.92	16.92
N	21	21	21	21	21	21
D Mean	4.63	4.63	7.25	7.25	11.88	11.88
SD	7.09	7.09	14.31	14.31	20.43	20.43
N	8	8	8	8	8	8
F	**13.65**	**36.60**	1.32	**4.91**	**5.12**	**16.39**
P value	**.000**	**.000**	.270	**.002**	**.002**	**.000**

When all diagnoses are combined there is a clear hierarchy of fear of hypoglycaemia with participants on insulin exhibiting a greater fear of hypoglycaemia than all other types of medication, and participants on sulphonylureas showing the next highest scores (Figure 3.8). There is little difference between participants on metformin and participants that are diet controlled.

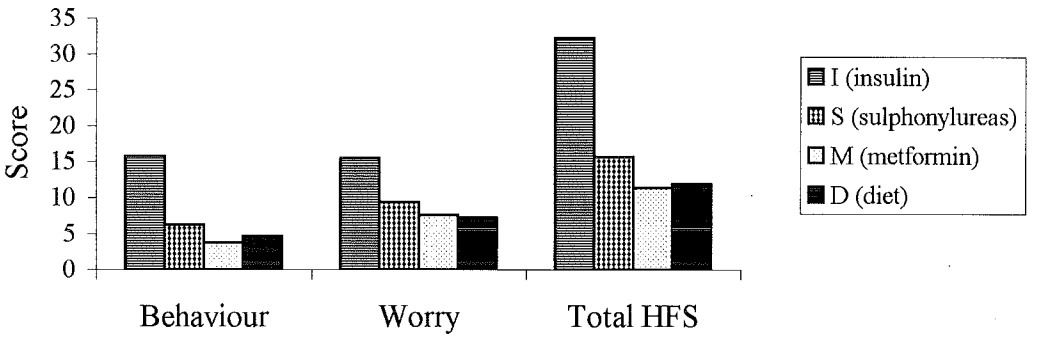

Figure 3.8. Relationship between types of diabetes medication and mean scores for the Behaviour andWorry Subscales and the Total HFS Score for all participants.

Participants who can experience hypoglycaemia score significantly higher on all three HFS scores compared to those who cannot (Table 3.12). However, in the group that cannot physiologically experience hypoglycaemia three participants scores fell in the high fear of glycaemia range.

Table 3.12. Comparison of HFS scores for participants that can and cannot experience hypoglycaemia.

	Behaviour Subscale	**Worry Subscale**	**Total HFS Score**
CANHYPO			
Can hypo Mean	14.49	14.68	29.18
SD	7.82	12.70	18.05
N=116	243	243	243
Can't hypo Mean	4.00	7.52	11.52
SD	5.35	13.20	17.58
N=156	29	29	29
F	**49.40**	**8.19**	**24.93**
p value	**.000**	**.005**	**.000**

When HbA_{1c} is put into categories to indicate goodness of metabolic control, there is a significant difference in the behaviour scores of the HFS (Table 3.13). Participants with good metabolic control have a lower mean behaviour subscale score than those that have fair and poor control. This was also found for the total HFS score. The mean differences in the worry scores were not significantly different between the three groups; however, the trend of the mean scores was in the direction of increasing scores associated with poor control. Multiple comparison analysis showed that the significant different found in the behaviour and total HFS subscales was due to differences between the "Good" group when compared to the "Fair" and "Poor" groups (Table 3.14).

Table 3.13. Results of the ANOVA between Metabolic Control and HFS Scores.

Metabolic Control	Behaviour Subscale	Worry Subscale	Total HFS Score
Good			
Mean	11.13	11.91	23.03
SD	8.11	13.53	19.10
N=86			
Fair			
Mean	14.72	14.72	29.45
SD	8.23	12.57	18.83
N=105			
Poor			
Mean	13.97	14.99	28.96
SD	8.07	12.68	17.93
N=80			
F	**4.928**	1.521	**3.26**
P value	**.008**	.220	**.040**

Table 3.14. Multiple comparisons for metabolic control categories for the behaviour and HFS total scores.

Dependent variable	Metabolic control		Mean difference	Significance (p)
Behaviour subscale	Good	Fair	-3.60	.003**
		Poor	-2.85	.025*
Total HFS	Good	Fair	-6.41	.019*
		Poor	-5.93	.042*

There was no relationship between any of the three HFS variables and depression medication.

Participants who reported that they took measures to avoid hypoglycaemia had significantly higher mean scores on all HFS measures, except for those with type 1 diabetes (Table 3.15). However, the number of participants with type 1 diabetes who did not take measures to prevent hypoglycaemia was very small.

Table 3.15. Comparison between HFS scores for participants with different levels of metabolic control.

	Behaviour Subscale			Worry Subscale			Total HFS Score		
	Type 1	Type 2	Type 1&2	Type 1	Type 2	Type 1&2	Type 1	Type 2	Type 1&2
Prevent Hypoglycaemia									
'Yes' Mean	19.00	13.03	16.60	17.95	13.32	16.09	36.95	26.34	32.70
SD	5.66	6.44	6.65	11.66	13.34	12.53	15.14	17.67	16.97
N	109	73	182	109	73	182	109	73	182
'No' Mean	14.71	6.18	6.84	16.43	8.94	9.52	31.14	15.12	16.37
SD	7.25	6.91	7.27	12.66	12.52	12.63	16.05	17.17	17.54
N	7	83	90	7	83	90	7	83	90
F	3.64	**40.61**	**121.83**	.122	**4.46**	**16.48**	.963	**16.14**	**54.52**
p value	.059	**.000**	**.000**	.739	**.036**	**.000**	.328	**.000**	**.000**
Experienced Hypoglycaemia									
'Yes' Mean	18.84	11.80	15.33	18.36	12.89	15.64	37.20	24.69	30.97
SD	5.65	7.10	7.31	11.60	13.62	12.91	15.02	18.21	17.79
N	111	110	221	111	110	221	111	110	221
'No' Mean	16.60	3.61	4.88	6.8	6.43	6.47	23.40	10.04	11.35
SD	9.53	4.83	6.60	7.53	10.37	10.07	13.94	13.71	14.17
N	5	46	51	5	46	51	5	46	51
F	.705	**51.18**	**87.80**	**4.85**	**8.31**	**22.53**	**4.06**	**24.03**	**54.07**
p value	.403	**.000**	**.000**	**.030**	**.005**	**.000**	**.046**	**.000**	**.000**
Help with Hypoglycaemia									
'Yes' Mean	19.71	16.41	18.83	20.36	20.41	20.37	40.07	36.81	39.21
SD	5.74	7.26	6.31	12.58	16.69	13.70	16.01	21.43	17.55
N	75	27	102	75	27	102	75	27	102
'No' Mean	16.98	7.84	10.11	13.29	8.95	10.12	30.27	16.78	20.23
SD	5.61	6.67	7.50	8.10	11.29	10.80	11.18	15.48	15.67
N	41	128	166	41	128	166	41	128	166
F	**6.01**	**18.69**	**96.12**	**10.53**	**9.73**	**46.23**	**12.11**	**16.61**	**84.51**
p value	**.015**	**.000**	**.000**	**.002**	**.000**	**.000**	**.001**	**.000**	**.000**

Participants who had experienced hypoglycaemia had significantly higher mean scores on all HFS scores except for the behaviour subscale for those with type 1 and again the number of those who had not taken measures to avoid hypoglycaemia was very small. Participants who had previously required help to

manage hypoglycaemia scored more highly that those that had not on all HFS scores.

Univariate analysis of variance shows that the model presented accounts for 55% of variance in the Total HFS score. The variables that have the strongest relationship are the HADS Anxiety Subscale ($F[1,12] = 57.84$, $p < .0001$), previous hypoglycaemia requiring help from others ($F[1,12] = 21.41$, $p < .0001$), and diagnosis ($F[1.12] = 6.11$, $p < .05$).

4. DISCUSSION

The results of this study add to the understanding of fear of hypoglycaemia and will be discussed in terms of the model presented earlier in figure 1.2. Before these results are interpreted it is useful to consider how representative the sample is with reference to diabetes clinic populations and that of people with diabetes in the community. The lack of independence between age and type of diabetes, and the nature of anxiety and depression in this population are also discussed.

4.1. How representative is the sample?

Maori and Pacific Island People were likely to be under represented compared to New Zealanders of European descent. There is no recent information of the ethnic identities of people attending the Christchurch Diabetes Centre, however, Lunt (1993) reported that Maori made up 6% of clinic attendees in 1991. Since this time diabetes has been increasing more rapidly in Maori than in people of European descent (Health Funding Authority, 2000) and so it was expected that Maori would account for more than 6% of patients attending the clinic. The present study included only 3 to 4% Maori participants. Pacific Island people made up only 2% of participants and are also likely to be under represented. Possible barriers leading to under representation of these ethnic minorities may include cultural differences in attitudes towards participating in research, and English as a second language for some Pacific Island people. Over-sampling of ethnic minorities is needed before results of studies into fear of hypoglycaemia can be generalised to these ethnic groups.

Ethnicity aside, the sample can be considered to be representative of people with diabetes who attend a tertiary diabetes clinic as the overall response rate was very good. Both genders are evenly represented and there is a wide age range included. Type 1 and type 2 diabetes are evenly represented, however, this reflects the clinic population rather than people with diabetes in the community. People with type 1 diabetes made up 43% of the sample but accounts for only five to ten percent of all people with diabetes in New Zealand (Health Funding Authority, 2000).

As a clinic population was used for the study, the participants are characteristic of people with diabetes that is more advanced or less well controlled. As such, this sample contained more people on insulin therapy (78%) than in the community (14%; Scott & Brown, 1991). The majority of participants had medication changes in the previous six months, which again reflects the more complex nature of patients attending the centre.

4.2. Age and diagnosis are not independent

Age and diagnosis are not independent variables. The mean age distribution of participants with type 1 diabetes is skewed towards the younger ages, whereas the distribution of age for type 2 diabetes is skewed towards the older ages. As type 1 diabetes is generally diagnosed in childhood through to young adulthood, there is a significant number of patients in this age group, with numbers decreasing with age. Type 2 diabetes is generally not diagnosed until middle adulthood and prevalence increases with increasing age, therefore there are very few patients with type 2 diabetes under the age of 30 years in this study, and numbers peak

around the 50 to 55 years age group. Therefore it is difficult to separate the effect of age from diagnosis unless each diagnosis is analysed separately.

4.3. Anxiety and depression in a diabetes clinic population

The HADS was found to be a quick and acceptable tool for assessing anxiety and depression in participants in this study. However when interpreting HADS results, it needs to be considered that the HADS is not a diagnostic test for anxiety or depression, rather it is an indication of whether further assessment of these conditions is required.

The levels of anxiety and depression in participants of this study indicated by the HADS were higher than that expected to be found in the general population. Sixteen percent of participants scored in the range for probable anxiety and 27% scored in the possible anxiety range, together accounting for 43% of the sample. The Christchurch Psychiatric Epidemiology Study (Oakley-Browne, Joyce, Wells, Bushnell, & Hornblow, 1989; Wells, Bushnell, Hornblow, Joyce, & Oakley-Browne, 1989) found that the six-month prevalence rate in the general population for anxiety disorders was 8.4%.

Depression rates were lower than anxiety in the present study with 3% of participants scoring in the probable range and 16% in the possible range, together accounting for 19% of the sample. The Christchurch Psychiatric Epidemiology Study (Oakley-Browne et al., 1989; Wells et al., 1989) found that the six-month prevalence rate in the general population for affective disorders was 9.4%.

The higher levels of anxiety and depression found in this study are in line with other studies that have also found levels of anxiety and depression are higher in medical populations than the general population (Herrmann, 1997). Another study of patients with diabetes found that 28% of patients with type 1 and type 2 diabetes had moderate to severe levels of anxiety, depression, or both as measured by the HADS (Lloyd, Dyer, & Barnett, 2000). Eggleston, (2002) investigated anxiety and depression in patients with cancer attending out-patient clinics at Christchurch Hospital and levels of anxiety (16% possible anxiety, 12% probable anxiety) and depression (9% possible and 5% probable depression) - also at higher levels than that in the general population.

In this study females scored more highly than males for anxiety but there was no difference for depression. This is consistent with results from the Christchurch Psychiatric Epidemiology Study (Oakley-Browne et al., 1989; Wells et al., 1989) that found females had more anxiety disorders when compared to men but there was no difference for depression. This pattern is also typically found in HADS results in other studies (for a review see Herrmann, 1997; diabetes Lloyd et al., 2000).

There was no significant difference in levels of anxiety or depression in participants with type 1 diabetes than participants with type 2 diabetes. This result is consistent with Lloyd et al., (2000) where no difference in HADS scores was found for patients with type 1 and type 2 diabetes. There was no relationship with duration of diagnosis, which is also consistent with Lloyd et al., (2000).

Despite finding no difference in anxiety or depression between participants with type 1 and type 2 diabetes, significantly more participants with type 2 were taking medication for anxiety or depression and these participants scored more highly on both subscales of the HADS. It is unclear why more participants with type 2 were on medications for anxiety or depression. This difference maybe due, at least in part, to the older average age of participants with type 2 diabetes.

There was no relationship of anxiety or depression with age. Lloyd et al., (2000) also found no linear relationship between anxiety or depression and age in patients with diabetes. However, epidemiological studies (Oakley-Browne et al., 1989) have found affective disorders increase with age whereas anxiety disorders remain relatively constant throughout the age range of 18 to 64 years.

There was a modest to strong correlation between previous hypoglycaemia and anxiety. Other cross sectional studies in different medical populations, including cancer and cardiac, have found anxiety correlated with the severity of symptoms (Herrmann, 1997). Depression was not correlated with previous hypoglycaemia.

Higher HbA_{1c} levels were correlated with higher anxiety scores only in participants with type 1 diabetes indicating a link between anxiety and metabolic control. Lloyd et al., (2000) also found that anxiety affected HbA_{1c} but only in men with high anxiety and moderate to severe depression. Depression was not correlated with HbA_{1c} in this study. As the analysis is correlational no causal conclusions can be drawn. It is possible that anxiety affects management of blood

glucose either at a behavioural or physiological level; however, high blood glucose levels could potentially cause people to feel more anxious.

Contrary to predictions, participants that lived alone did not score more highly for anxiety or depression. Previous studies had found an association between HADS scores and psychosocial factors (Herrmann, 1997). Living alone may be a psychosocial stressor for some but not all participants.

In summary, the results of the HADS in this study are consistent with other studies that indicate that levels of anxiety and depression are higher in medical populations than the general population. Females scored more highly for anxiety than men but there was no difference between sexes for depression. There was also no difference between participants with type 1 and type 2 diabetes despite more of those with type 2 taking medication for anxiety or depression, and a greater average age. Previous experiences of hypoglycaemia and higher HbA_1c have also been found to be associated with anxiety (but not depression) in some participant groups. Correlational analysis does not allow testing of causal relationships and so the nature of these relationships remains speculative.

4.4. Prevalence of fear of hypoglycaemia

Eighteen percent of participants had a high fear of hypoglycaemia. It is difficult to compare this result to other studies for the following reasons:

- There are several different versions of the HFS that have been used by different studies. Differences with the Worry Subscale are the most prevalent differences with some studies using a 13 item version (e.g. the present study; Cox,

Gonder-Frederick, Nowacek, & Butterfield, 1987; Irvine, Cox, & Gonder Frederick, 1990; Irvine, Cox, & Gonder Frederick, 1994; Polonsky, Davis, Jacobson, & Anderson, 1992; Ter Braak et al., 2000) whereas others have used a 17 item Worry Subscale version (e.g. Hepburn, Deary, MacLeod, & Frier, 1994; Irvine, Cox, & Gonder Frederick, 1992; Shiu & Wong, 2000).

- Different criteria are used to define a fear of hypoglycaemia. This study has used one standard deviation above the mean as an arbitrary cut-off point. (Shiu & Wong, 2000) also used one standard deviation above the mean and found that 15% of their sample had a high fear of hypoglycaemia. Most other studies have not defined a cut-off for a high level of fear.

- Different studies have adapted the HFS to suit their own population. For example, Green, Wysocki, & Reineck, (1990) made adaptations for a child population, and translations have been made into Romanian (Costea et al., 1993), and Mandarin (Shiu & Wong, 2000). The present study also adapted the scale to suit a New Zealand population by replacing North American terms with those used in New Zealand.

Despite the above problems, mean scores of subscales can be compared for a number of studies. Early studies using the HFS reported scores for the behaviour and worry subscales that were greater than those found in this study (Cox et al., 1987; Irvine et al., 1990; Irvine et al., 1994; Polonsky et al., 1992). However, Ter Braak et al., (2000) reported results for the Worry Subscale that were similar to this study. Most of the earlier studies only surveyed patients with type 1 diabetes

which may have lead to higher scores, however, when type 1 scores from this study are compared, the scores from the present study are still lower. This could be due to differences in recruitment methods or may reflect a cultural difference.

Some studies have discarded the Behaviour Subscale and have used the Worry Subscale as a stand-alone measure of fear of hypoglycaemia. The Behaviour Subscale is not a pure linear measure as it contains some items that are important for good metabolic control and should always be done (e.g. item 8. "I carry fast acting sugar with me"), other items that should be done when appropriate or in moderation (e.g. item 9. "I avoid exercise when I think my blood sugar is low") and others that are inappropriate (e.g. item 3. " if I test my blood sugars, I keep them a little high to be on the safe side"). In contrast the Worry Subscale is straight forward and is a simple measure of how often people worry about different aspects of diabetes (e.g. item 11. "I worry about not recognising/ realising I am having a low blood sugar"). There is a correlation between the two subscales, indicating a link between worry and behaviour. However, both subscales provide different and useful information in the analysis of fear of hypoglycaemia. The present study shows that each subscale has different relationships with different factors. For example, behaviour is correlated with HbA_{1c} in participants with type 1 diabetes whereas the Worry Subscale is not.

As a research and clinical tool the HFS is acceptable to patients and is quickly completed. It provides useful information at a clinical level, particularly as a quick assessment of behaviour that may be compromising diabetes management. However, as a research tool there needs to be a version that is consistently used to

enable direct comparisons between studies. More research is needed into developing normative scores and cut-off scores for both high fear and low fear that are meaningful at a clinical level.

4.5. Fear of hypoglycaemia model

The model presented in figure 1.2 describes the predicted influence of factors on fear of hypoglycaemia. The factors that were predicted to have the largest positive effect on fear of hypoglycaemia were previous experience of hypoglycaemia, severity of hypoglycaemia, type 1 diabetes, medications with hypoglycaemic action, anxiety, depression and living alone. The characteristics of each of these variables and their relationship with fear of hypoglycaemia are discussed below.

4.5.1. Previous hypoglycaemia

Almost all participants with type 1 diabetes (94%) had taken measures to prevent hypoglycaemia. It was expected that all type 1 participants would have taken such measures as all were on insulin therapy. Fewer participants with type 2 diabetes (47%) had taken measures to avoid hypoglycaemia. As 11% of participants with type 2 diabetes were not taking medication with a hypoglycaemic action and therefore should not experience hypoglycaemia, not taking measures may be an appropriate response. However, for the remaining 6% of participants with type 1 diabetes and 32% of participants with type 2 diabetes that may experience hypoglycaemia due to medication effects, by not taking measures to avoid hypoglycaemia they are at risk of hypoglycaemic episodes.

Almost all participants with type 1 diabetes (96%) and the majority of those with type 2 diabetes (71%) had previously experienced hypoglycaemia, indicating that most patients are at risk of hypoglycaemia if their diabetes is not well controlled.

Significantly more participants with type 1 diabetes had required help to manage hypoglycaemia than participants with type 2 diabetes (65% and 17% respectively). This reflects the increased risk of hypoglycaemia for people with type 1 diabetes compared to type 2 diabetes.

Overall the responses from participants confirm that people with type 1 diabetes experience hypoglycaemia more often and when they do it is likely to be more severe. This experience is likely to increase the likelihood of developing fear of hypoglycaemia in type 1 diabetes compared to type 2.

The link between experience of hypoglycaemia and increased HFS scores was found in all participants with type 1 and type 2 diabetes in this study. Other studies have also found that previous experience of hypoglycaemia has an important association with fear of hypoglycaemia measures. Gold et al., (1997) found a history of severe hypoglycaemia accounted for over 25% of variance on the worry subscale in patients with IDDM. Ter Braak et al., (2000) also found those with more severe hypoglycaemia experience had significantly higher mean scores on the HFS worry.

The results from this study support the prediction that previous experience and severity of hypoglycaemia is involved with the development of fear of hypoglycaemia.

4.5.2. Diagnosis

As expected, diagnosis had a large effect on fear of hypoglycaemia. Participants with type 1 diabetes on average scored higher than participants with type 2 diabetes on all measures of the HFS. This has also been found by all other studies that have compared participants with type 1 and type 2 diabetes (Polonsky et al., 1992; Shiu & Wong, 2000). As discussed above, patients with type 1 diabetes are more likely to experience hypoglycaemia, particularly more severe episodes, than patients with type 2 diabetes. Therefore this group are more likely to develop a phobic response to hypoglycaemia.

The duration of diagnosis was a factor that had an unpredicted effect on fear of hypoglycaemia. The results show that duration of diagnosis has a modest correlation with the Behaviour Subscale for participants with type 2 diabetes. As participants with type 2 diabetes progress to sulphonylureas and/or insulin therapy the risk of hypoglycaemia increases and it becomes necessary to change behaviour to avoid hypoglycaemia. In contrast, participants with type 1 are on insulin from the time of diagnosis and so have had to behaviourally manage the risk of hypoglycaemia from that time. There is no association between duration of diagnosis and the Worry Subscale, which indicates that worry about hypoglycaemia does not significantly lessen or increase over time.

4.5.3. Medication

The risk of hypoglycaemia associated with different diabetes medications was predicted to effect HFS scores, with those patients taking insulin and

sulphonylureas predicted to have greater fear than those on metformin or diet only. The results indicate that there is a hierarchy of fear according to action of medication. Participants on insulin showed the greatest mean HFS scores, followed by sulphonylureas and lastly there was little difference between metformin and diet only. This was consistent with the results from comparing participants that can experience hypoglycaemia compared to those that cannot. However, three participants that should not be able to experience hypoglycaemia did have a fear of hypoglycaemia. It seems possible that patients can develop a fear of hypoglycaemia vicariously. Misinformation or experiences of hypoglycaemia from friends, family, other diabetics and the media may all provide situations where a fear can develop in someone that cannot experience hypoglycaemia. It is also possible that some people may have misunderstood the HFS questionnaire.

4.5.4. Anxiety and depression

Anxiety and depression were predicted to have a positive effect on fear of hypoglycaemia. The results show that anxiety has moderate to large correlation with HFS scores, especially with the worry subscale, and anxiety is the factor that loads highest on fear of hypoglycaemia in multivariate analysis. This result indicates the close relationship between fear of hypoglycaemia and other anxiety traits. It seems likely that patients who develop a high fear of hypoglycaemia may have a predisposition towards anxiety. Depression has a moderate correlation with the HFS, and this is not surprising considering there is a correlation between the anxiety and depression subscale of the HADS.

4.5.5. Living alone

Patients that lived alone were predicted to score more highly on the HFS, however, this was not supported by the results. Participants who lived alone were no more likely to have a fear of hypoglycaemia than those that were not living alone. This was surprising as this group has a greater risk of complications from severe hypoglycaemia such as coma, particularly at night as there is no one else present to help them manage a severe hypoglycaemic episode.

4.5.6. Ethnicity

Whether ethnicity would have an influence on HFS scores was unpredicted by the model of fear of hypoglycaemia. There did appear to be differences in HFS scores for different ethnic groups, however, they were unable to be analysed statistically due to small sample sizes. The results are reported because they indicate that there may be differences between ethnic groups that could be investigated further. Maori had lower average scores on the Behaviour Subscale than participants of European descent. If this is a significant difference it could place Maori at greater risk of experiencing hypoglycaemia. However, Maori and participants of European decent had similar Worry Subscale scores. Pacific Island participants' average score fell between that of Maori and those of European descent but the average Worry score was lower than both of the other groups. These results suggest that there may be differences between these groups in the prevalence and presentation of fear of hypoglycaemia.

4.5.7. Age

Age was another variable that did not have a predicted effect on fear of hypoglycaemia. Results show that age is negatively correlated with scores on the HFS when type 1 and type 2 diabetes are analysed together, however this is an artefact of diagnosis as when type 1 and 2 results are analysed separately there is no relationship between age and HFS scores.

4.5.8. Sex

Females scored higher on all measures of the HFS except for the Behaviour Subscale in participants with type1. Females generally score more highly on anxiety measures than males. Females may also have better self-care behaviours and therefore may score more highly on Behaviour Subscale. However, there was no difference between males and females with type 1 diabetes on the Behaviour Subscale, possibly due to needing to manage their blood glucose levels more closely than participants with type 2 diabetes. Although sex had an unpredicted effect on HFS scores the results indicate that females score more highly on average than males.

In summary the factors that have the strongest relationship with fear of hypoglycaemia as measured by the HFS are previous experience and severity of hypoglycaemia, type 1 diabetes and general anxiety. Factors that have a smaller positive relationship are medications that can cause hypoglycaemia (insulin and sulphonylureas), depression, and being female. Factors that have no or mixed effects are age, duration of diagnosis, and living alone. Fear of hypoglycaemia may be different for different ethnicities, however this is still unclear.

4.6. Metabolic control and fear of hypoglycaemia

Metabolic control was predicted to be associated with a high fear of hypoglycaemia. Overall most participants (68%) had undesirable metabolic control (HbA_{1c} greater than $7mmolL^{-1}$) and had an increased risk of developing hyperglycaemia related complications. Participants with type 1 diabetes had a higher average HbA_{1c} than participants with type 2 diabetes, however the difference was small and not likely to be clinically useful. Almost all participants had a blood-testing machine and therefore could monitor blood glucose levels regularly if they chose to do so.

Results show that HbA_{1c} is only correlated with scores on the HFS when both diagnoses are combined. However, participants with good control scored significantly lower on HFS subscales than those with fair and poor control. This result suggests that there is a link between fear of hypoglycaemia and higher blood glucose levels; however, fear of hypoglycaemia may influence HbA_{1c} in some but not all patients. There are many other factors that can influence metabolic control as previously discussed.

4.7 Treatment of fear of hypoglycaemia suggested by the results of this study

The results of this study suggest the following approaches may be helpful to the treatment of people with a high fear of hypoglycaemia:

- Education - diabetes consultants already commonly provide education about hypoglycaemia management and the risks associated with hyperglycaemia. However, patients with an inappropriate fear of hypoglycaemia may need a greater emphasis on education about these topics. It is also important to recognise that some patients that cannot experience hypoglycaemia were found to have a high fear of hypoglycaemia and this indicates that such information needs to be given to patients regardless of their diabetes treatment.

- The significant relationship between fear of hypoglycaemia and anxiety in general indicates that at least some patients with a high fear of hypoglycaemia are likely to have other problems with anxiety. It is possible that a general approach to anxiety management may be useful when treating these patients.

- Given that almost 1 in 5 patients of the participants in this study had a high fear of hypoglycaemia it seems likely that treatment directed at fear of hypoglycaemia specifically may be helpful for at least some of this group, and may be beneficial to metabolic control.

4.8. Future research

All of the previous studies investigating fear of hypoglycaemia have used a cross sectional design. In order to develop and test the theories about the causes of fear of hypoglycaemia a longitudinal design may be useful. This would enable causation to be investigated.

Better measures of glycaemic control need to be employed. Regular blood glucose testing at intervals throughout the day may be more helpful and give a more realistic indication of daily fluctuations and the risks to individuals of hypoglycaemia.

Anxiety in this study was measured by the HADS, which indicates the level of anxiety over the previous week. It is possible that anxiety about attending the appointment at the diabetes centre, or other life stressors may have resulted in elevated anxiety scores on this instrument. Future studies could investigate anxiety with measures that are more reflective of trait anxiety to limit these effects.

Diabetes complications were not investigated in this study. However, it may be useful in future studies to record the level of hyperglycaemic related complications in people with a fear of hypoglycaemia and compare it to those without fear of hypoglycaemia in order to investigate a link between fear of hypoglycaemia and increased diabetes related complications as predicted by the model presented.

4.9. Conclusion

Fear of hypoglycaemia was found to be a reasonably common phenomenon in patients attending the Christchurch Diabetes Centre. People with a high fear of hypoglycaemia were more likely to score highly on the anxiety subscale of the HADS. This suggests that people who develop a fear of hypoglycaemia are more anxious in general than those that do not develop a fear of hypoglycaemia.

Environmental factors such as previous experience of hypoglycaemia, either directly or vicariously, can trigger this underlying vulnerability. Fear of hypoglycaemia may result in poor metabolic control in some patients, however, there are many other factors that also influence metabolic control and more research is needed in this area.

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APPENDIX A

Patient Information Sheet

Patient Consent Form

Canterbury HEALTH
Manaaki tatou • Caring for everyone

Fear of Low Blood Sugar (Hypoglycaemia) in People who attend the Christchurch Diabetes Centre

Information Sheet

You are invited to take part in a study to find out how many people who attend the Christchurch Diabetes Centre have a fear of low blood sugar (hypoglycaemia or hypo). We want to see if fear of low blood sugar is related to medication, type of diabetes, diabetes control or mood. All people who attend a clinic appointment at the Diabetes Centre between November 2000 and February 2001 will be invited to take part.

When you attend your clinic appointment you will be asked if you are willing to take part in the study. The study involves completing two short questionnaires. The first looks at how much people worry about low blood sugars (hypo's) and what they do to avoid them. The second asks about mood and anxiety. You do not have to answer any questions you do not wish to. Your clinic notes will also be viewed and the HbA1c blood test from that appointment will be recorded. This study is part of an Otago University Christchurch School of Medicine Summer Studentship. This study has received ethical approval from the Canterbury Ethics Committee.

Your participation is entirely voluntary (your choice). If you decide to participate, you may withdraw at any time without having to give a reason and this will not affect your future health care. You do not have to take part in this study, and if you choose not to take part you will receive your usual care. If you do agree to take part you will be given two questionnaires to complete while you wait for your appointment. The questionnaires take between 10 to 20 minutes to complete. You will also be asked the names of your diabetes medication (if you take any). You can bring a support person to help you fill out the questionnaires. If you have any queries or concerns about your rights as a participant in this study you may wish to contact a health and Disability Advocate, telephone (03) 377 7501 or 0800377 766 (outside Christchurch).

You will be asked if you want your questionnaire results and a summary of all results. You will also be asked if you are happy for your GP to be sent the results of your questionnaire. There may be a delay between you completing the questionnaires and the results being available. All questionnaires will be kept in a locked filing cabinet. No material which could personally identify you will be used in any reports on this study.

Please feel free to contact the researcher if you have any questions about this study.

Joss Tennent

Joss Tennent
Senior Clinical Psychologist
Lead Investigator
September 2000

Diabetes Centre
Corner Oxford Terrace & Antigua Street, Private Bag 4710, Christchurch, N.Z.
Telephone: (03) 364 0860 Fax: (03) 364 0171

Canterbury HEALTH
Manaaki tatou • Caring for everyone

Fear of Low Blood Sugar (Hypoglycaemia) in People who attend the Christchurch Diabetes Centre

Consent Form

I have read and I understand the information sheet dated September 2000 for volunteers taking part in the study designed to assess how common fear of low blood sugar (hypoglycaemia) is in people who attend the Christchurch Diabetes Centre. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my continuing health care.

I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study.

I have had time to consider whether to take part. I know whom to contact if I have any side effects to the study.

I give permission for my GP to be sent a copy of my results	yes	no
I wish to receive a copy of my questionnaire results	yes	no
I wish to receive a copy of the study results	yes	no

I _____ (full name) consent to take part in this study.

Signed:

Date:

Researcher:

Researcher's signature:

Date:

Diabetes Centre
Corner Oxford Terrace & Antigua Street, Private Bag 4710, Christchurch, N.Z.
Telephone: (03) 364 0860 Fax: (03) 364 0171

APPENDIX B

Demographic and diabetes questions

Hospital Anxiety and Depression Scale

Hypoglycaemia Fear Survey

The following are some general questions about you and your diabetes.

When was your diabetes first diagnosed?

What medication are you prescribed for your diabetes?

When did you last change your diabetes medications?

Are you currently taking medication for anxiety, low mood or depression? ..... Yes ..... No

If yes, what is the medication?

Have you ever done anything to prevent a hypo? ..... Yes No

Have you ever had any symptoms that you thought may be a hypo (low blood sugar)? Yes No

If you have not had a hypo yourself, what do you think might happen if you did?

Have you ever had a hypo where someone needed to help you manage it?.... Yes No

Have you got a blood glucose machine for testing your blood sugars? ..... Yes No

Do you live alone?..... Yes No

What ethnic group do you identify with? (Please tick)

- ☐ Maori
- ☐ NZ European/Pakeha
- ☐ Pacific Island _____
- ☐ Other _____

Hospital Anxiety and Depression Scale (HADS)

NFER-NELSON
INFORMING YOUR DECISIONS

Name: _____ Date: _____

Clinicians are aware that emotions play an important part in most illnesses. If your clinician knows about these feelings he or she will be able to help you more.

This questionnaire is designed to help your clinician to know how you feel. Read each item below and **underline the reply** which comes closest to how you have been feeling in the past week. Ignore the numbers printed at the edge of the questionnaire.

Don't take too long over your replies, your immediate reaction to each item will probably be more accurate than a long, thought-out response.

FOLD HERE

FOLD HERE

A D

I feel tense or 'wound up'
- Most of the time — 3
- A lot of the time — 2
- From time to time, occasionally — 1
- Not at all — 0

I still enjoy the things I used to enjoy
- Definitely as much — 0
- Not quite so much — 1
- Only a little — 2
- Hardly at all — 3

I get a sort of frightened feeling as if something awful is about to happen
- Very definitely and quite badly — 3
- Yes, but not too badly — 2
- A little, but it doesn't worry me — 1
- Not at all — 0

I can laugh and see the funny side of things
- As much as I always could — 0
- Not quite so much now — 1
- Definitely not so much now — 2
- Not at all — 3

Worrying thoughts go through my mind
- A great deal of the time — 3
- A lot of the time — 2
- Not too often — 1
- Very little — 0

I feel cheerful
- Never — 3
- Not often — 2
- Sometimes — 1
- Most of the time — 0

I can sit at ease and feel relaxed
- Definitely — 0
- Usually — 1
- Not often — 2
- Not at all — 3

A D

I feel as if I am slowed down
- Nearly all the time — 3
- Very often — 2
- Sometimes — 1
- Not at all — 0

I get a sort of frightened feeling like 'butterflies' in the stomach
- Not at all — 0
- Occasionally — 1
- Quite often — 2
- Very often — 3

I have lost interest in my appearance
- Definitely — 3
- I don't take as much care as I should — 2
- I may not take quite as much care — 1
- I take just as much care as ever — 0

I feel restless as if I have to be on the move
- Very much indeed — 3
- Quite a lot — 2
- Not very much — 1
- Not at all — 0

I look forward with enjoyment to things
- As much as I ever did — 0
- Rather less than I used to — 1
- Definitely less than I used to — 2
- Hardly at all — 3

I get sudden feelings of panic
- Very often indeed — 3
- Quite often — 2
- Not very often — 1
- Not at all — 0

I can enjoy a good book or radio or television programme
- Often — 0
- Sometimes — 1
- Not often — 2
- Very seldom — 3

Now check that you have answered all the questions

A D

TOTAL

Code 4460 01 4 Printed in Great Britain 1(6.94)

II. **Worry** Below is a list of concerns people with diabetes sometimes have. Please read each item carefully (do not skip any). Circle one of the numbers to the right that best describes how often you worry about each item because of low blood sugar.

	I worry about...	Never	Rarely	Sometimes	Often	Always
11.	Not recognising / realising I am having a low blood sugar	0	1	2	3	4
12.	Not having food, fruit, or juice with me	0	1	2	3	4
13.	Passing out in public	0	1	2	3	4
14.	Embarrassing myself or my friends in a social situation	0	1	2	3	4
15.	Having a reaction (hypo / low blood sugar) while alone	0	1	2	3	4
16.	Appearing stupid or drunk	0	1	2	3	4
17.	Losing control	0	1	2	3	4
18.	No one being around to help me during a reaction (hypo / low blood sugar)	0	1	2	3	4
19.	Having a reaction (hypo / low blood sugar) while driving	0	1	2	3	4
20.	Making a mistake or having an accident	0	1	2	3	4
21.	Getting a bad evaluation or being criticised	0	1	2	3	4
22.	Difficulty thinking clearly when responsible for others	0	1	2	3	4
23.	Feeling light-headed or dizzy	0	1	2	3	4

This part of the survey may or may not apply to you. If particular questions do not apply to you, circle the "Never" answer.

Low Blood Sugar Survey

I. Behaviour: Below is a list of things people with diabetes do in order to avoid low blood sugar. Read each item carefully. Circle one of the numbers to the right that best describes **what you do during your daily routine** to **AVOID** low blood sugar.

		Never	Rarely	Sometimes	Often	Always
1.	I eat large snacks at bedtime	0	1	2	3	4
2.	I avoid being alone when my blood sugar is likely to be low	0	1	2	3	4
3.	If I test my blood sugars, I keep them a little high to be on the safe side	0	1	2	3	4
4.	I keep my blood sugars high when I will be alone for a while	0	1	2	3	4
5.	I eat or drink something as soon as I feel the first sign of low blood sugar	0	1	2	3	4
6.	I reduce my insulin when I think my blood sugar is low	0	1	2	3	4
7.	I keep my blood sugar high when I plan to be in a long meeting or at a party	0	1	2	3	4
8.	I carry fast-acting sugar with me	0	1	2	3	4
9.	I avoid exercise when I think my blood sugar is low	0	1	2	3	4
10	I check my blood sugar often when I plan to be in a long meeting or out to a party	0	1	2	3	4